EXPERT REPORT OF BRIAN RUCKER

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

Cobb County v. Purdue Pharma, et al.

Case No. 1:18-op-45817-DAP

JUNE 24, 2024

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I. Introduction

I, Brian R. Rucker, am the President of DEA Audit Group, LLC, located in Scottsdale, AZ. As a DEA compliance expert, I specialize in top-to-bottom reviews of controlled substance programs for manufacturers, wholesalers, and pharmacies.

I have been retained by Publix Super Markets, Inc. (Publix) in the matter In Re National Prescription Opiate Litig., No. l 7-MD-2804. Specifically, I was asked to review the evolution of the Publix suspicious order monitoring ("SOM") program, the history of DEA investigations, and the distribution and dispensing data maintained by Publix in order to opine on Publix's efforts to comply with the Controlled Substances Act ("CSA") and its regulations (the "Regulations") as a self-distributor[1] of prescription opioids to Publix pharmacies in Cobb County, Georgia. Additionally, I was asked to evaluate Plaintiff's experts' opinions with respect to Publix as a self-distributor of controlled substances. In doing so I note that Plaintiff's experts Lacey R. Keller,[2] Anna Lembke, M.D.,[3] Carmen A. Catizone, MS, RPh, DPh,[4] and Katherine Keyes, Ph.D.,[5] through their respective reports and deposition testimony, confirm that they do not opine or analyze Publix's role as a self-distributor of controlled substances. Additionally, while Plaintiff's expert Craig J. McCann, Ph.D., CFA is the only one of Plaintiff's experts to analyze distribution data, Dr. McCann confirmed he has no substantive opinion on Publix as a self-distributor based on his data

[1] Publix has only ever performed intra-company transfers of controlled substances from a centralized warehouse in Orlando, FL to Publix-owned pharmacies.

[2] Ms. Keller confirmed she "didn't do any analysis with respect to Publix as a distributor[.]" (Dep. Tr. L. Keller 15:1-10 (May 23, 2024)).

[3] Dr. Lembke confirms she "is not offering a specific opinion on Publix's role as a distributor." (Dep. Tr. A. Lembke 13:9-11 (May 16, 2024)).

[4] Dr. Catizone confirmed he is not "providing opinions regarding Publix's distribution practices of opioids from its warehouse to its stores[.]" (Dep. Tr. C. Catizone 138:5-9 (May 30, 2024)).

[5] Dr. Keyes confirmed her report and opinions reflect only "an overview of pharmacy dispensing and its association with various opioid-related outcomes." (Dep. Tr. K. Keyes 17:12-15 (May 14, 2024)).

analyses or otherwise.[6] Indeed, based on my review none of Plaintiff's experts have any substantive opinions whatsoever based on Dr. McCann's analysis of Publix as a self-distributor.[1] Moreover, none of Plaintiff's disclosed experts provide a qualitative analysis of Dr. McCann's suspicious order flagging methods.[7] Therefore, there is no way to prepare a rebuttal to Plaintiff's unarticulated view, if there is one, of the meaning or interpretation of Dr. McCann's analysis. As such, my report and opinions herein respond to the testimony, analyses, and opinions held by Plaintiff's remaining expert: Joseph Rannazzisi.

II. Background

A. Qualifications

I was an active duty officer in United States Navy from 1981 to 1985. From 1986 to 1997, I worked in the private sector for a defense contractor, and I also owned a printing company. I was recalled to active duty in 1997. I served in the United States Naval Reserves until 2000, and I retired with the rank of Commander in 2000. In 1997, I took a position as a Special Investigator with the U.S. Investigation Services, Inc., and I handled national security and public trust background investigations for federal employees on behalf of the United States Office of Personnel Management. Subsequent to leaving my position as Special Investigator, I joined the DEA as a Diversion Investigator.

[6] Dr. McCann confirmed "as an expert witness, [I] don't have any qualitative conclusions about that data [] or those calculations. I have a lot of quantitative conclusions that are embodied in the tables and graphs in the body of the text and in the appendices" and that he otherwise has "no idea" about other SOM algorithms beyond what was provided to him by Plaintiffs' lawyers. (Dep. Tr. C. McCann 28:5-16 (May 15, 2024)).

[7] Mr. Rannazzisi confirmed he "didn't look at any statistics or data to come up with [his] opinions" because, in his own words, he "didn't have to." (Dep. Tr. J. Rannazzisi 82:6-12 (May 30, 2024)). Additionally, Mr. Rannazzisi confirmed he did not "analyze the SOM flagging methods used by Dr. McCann in his report" and "didn't make a determination about whether or not the SOM flagging methods he used comply with the Controlled Substances Act or its regulations" (*id.* at 321:10-19). Plaintiff's remaining experts did not opine on or discuss Publix's conduct as a distributor, and thus offer no opinion as to Publix's suspicious order monitoring activities. *Supra* n. 2-5.

From December 1999 to December 2008, I was assigned to the DEA Philadelphia Field Division. During that time, I conducted criminal, civil, regulatory, and administrative investigations involving violations of the CSA. I performed numerous controlled substance and listed chemical regulatory inspections and audits of major pharmaceutical manufacturers, distributors, pharmacies, narcotic treatment programs, DATA-waived physicians, importers, exporters, researchers, and analytical labs throughout Eastern Pennsylvania and Delaware. I conducted civil investigations of pharmacies and hospitals. I also served as the lead investigator for two multi-agency domestic and international Internet Pharmacy criminal cases as well as multiple criminal cases involving the illicit prescribing of controlled substances. Several cases garnered the attention of the local and national media. In addition, I conducted basic diversion training for Pennsylvania and Delaware State and local law enforcement.

In January 2009, I was promoted to Staff Coordinator at DEA's Special Operation Division (SOD) in Northern Virginia where I coordinated DEA's most significant multi-jurisdiction, multi-nation, multi-agency pharmaceutical and chemical investigations. In February 2011, I was temporarily assigned to assist in an operation I was coordinating at SOD, known as "Operation Pill Nation," which resulted in the dismantling of numerous pill mills and rogue pharmacies in southern Florida. I also assisted with conducting diversion training at the DEA Training Academy in Quantico, VA for Special Agents, Task Force Officers and Diversion Investigators.

From December 2011 to August 2013, I was assigned to the Savannah Regional Office in the Atlanta Field Division as a Diversion Group Supervisor. My region encompassed 67 counties in Southern and Eastern Georgia, which included responsibility for approximately 8,500 DEA registrants. My group was responsible for conducting regulatory inspections of manufacturers, exporters, distributors, narcotic treatment programs, and DATA-Waived physicians. In addition,

my group conducted civil and criminal investigations of rogue pharmacies, practitioners and "pill mills." I also conducted pain management prescribing seminars for Georgia physicians and pharmacists in conjunction with State and local law enforcement and regulatory agencies.

During my employment with the DEA, I completed several courses of instruction including, but not limited to, DEA Basic Diversion School, Diversion Asset Forfeiture Training, DOJ Internet Drug Diversion Seminar, Advanced Diversion Investigator School, Tactical Diversion Squad Management Training, and Diversion Comprehensive Regulatory Investigations Class. Throughout my tenure, I received six Exceptional Performance Awards, two Superior Performance Awards, and two Certificates of Appreciation from the U.S. Attorney's Office, Eastern District of Pennsylvania.

Following my postponed retirement from DEA, I became the Director of Compliance for Independent Pharmacy Cooperative ("IPC") where I was employed from September 2013 to April 2018. IPC sold prescription drugs and over-the-counter products to over 6,400 independent pharmacies. I developed their controlled substance distribution program from the ground up, developing standard operating procedures for the shipment, receipt and storage of controlled substances, physical security requirements, auditing procedures, new customer onboarding procedures, threshold development, and DEA record-keeping and reporting procedures. In addition, I developed a suspicious order monitoring system comprised of monitoring techniques, due diligence procedures, dispensing data reviews, and pharmacy site visits. As part of the program, I conducted numerous pharmacy site visits as both an investigator and trainer of new contractors.

After departing IPC in April 2018, I established the DEA Audit Group, LLC to provide compliance consulting services to the pharmaceutical industry. I have provided guidance to

manufacturers and distributors regarding controlled substance compliance programs, suspicious order monitoring techniques and reporting, pharmacy enhanced due diligence, pharmacy on-boarding and site visit procedures, case information management development, compliance team training, and security valuations.

I have also been engaged on multiple occasions to provide continuing education training and presentations to independent pharmacists, manufacturers and distributors. Finally, I am the former Vice-President of the Arizona Chapter of the National Association of Drug Diversion Investigators ("NADDI"). The objective of NADDI is to improve its members' ability to investigate, prosecute, and prevent pharmaceutical diversion.

A copy of my complete curriculum vitae is attached hereto as **Exhibit A**.

B. Materials Considered

A copy of the materials I considered is attached hereto as **Exhibit B**. As noted therein, I reviewed all documents and information listed on Joseph Rannazzisi's Track 8 Materials Considered in addition to the other materials listed on Appendix B.

C. Compensation

I am being compensated by Publix at the rate of $550 per hour for time spent at deposition and trial and $450 per hour for all other work. During the past four years, I have not testified as an expert at trial or by deposition.

III. Overview

In order to assess Publix's policies and practices as a self-distributor of controlled substances, it is first necessary to understand the CSA and its Regulations as well as the DEA's responsibility in enforcing and providing guidance on the same. There are three key factors critical to understanding the CSA, and thus Publix's conduct as a self-distributor. First, the CSA requires registrants to create and maintain a SOM system that accomplishes the goal of preventing the

diversion of controlled substances. Second, the DEA does not endorse any specific SOM system. Third, the DEA and the CSA do not set forth any specific requirements for diligence or the reporting of suspicious orders. However, current proposed rulemaking suggests the DEA may eventually – and for the first time – publish a set of specific requirements for reporting suspicious orders and conducting due diligence.

With the above understanding, I analyzed Publix's current and historic SOM systems and processes from 2006 to approximately 2020. As set forth more fully below, Publix, a self-distributor of only Schedule III-V controlled substances from 2005-2016 and a self-distributor of only Schedule II-V controlled substances from 2016 to present, has continued to implement, improve, and evolve its SOM system and processes since it began self-distributing. Since 2005, Publix has never been subject to an adverse action by any governmental organization or entity for its practices related to the self-distribution of controlled substances nor have any of the seven DEA regulatory inspections found Publix was not in compliance with the Regulations. Rather, since 2005 Publix has continued to improve and evolve its SOM system to in a way that allows Publix, as a self-distributor, to adhere to the goal of preventing the diversion of controlled substances and continue to comply with the CSA and its Regulations. Taking this into account, and after reviewing the ARCOS data and Publix's dispensing data, it is evident that Publix has made an effort to, and succeeded in, complying with the CSA requirements and Regulations regarding Suspicious Order Monitoring and that such efforts have allowed it to prevent the diversion of controlled substances dispensed from Publix pharmacies.

IV. The Controlled Substances Act, Regulatory Framework, and Role of the DEA in Enforcing the CSA

A. Overview of the Controlled Substances Act and Regulations

In 1970, the CSA was signed into law by President Richard Nixon to regulate the manufacturing, distributing, importing/exporting, and use of controlled substances. In doing so, the CSA established schedules for controlled substances based on the medical use at the time and the potential for abuse and dependence. Highly addictive controlled substances with no medical use, such as heroin and marijuana, were placed into Schedule I whereas controlled substances with an accepted medical use were placed into Schedules II-V depending on their propensity for abuse and dependence.[8]

The CSA also requires all manufacturers, distributors, dispensers, and practitioners to register with the DEA in an effort to create a "closed system" to control the manufacturing, distributing, and dispensing of controlled substances.[9] As such, the DEA has the duty to deny or revoke a distributor's registration if it has acted in a manner "inconsistent with the public interest"[10] taking into consideration a number of factors, including whether the distributor has maintained "effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[11]

The CSA also expressly authorizes the DEA "to promulgate rules and regulations…relating to the registration and control of the manufacture, distribution and dispensing of controlled

[8] All controlled substances have a potential for abuse and dependence with Schedule II having the highest potential for abuse and Schedule V having the lowest.

[9] 21 U.S.C. § 823.

[10] 21 U.S.C. §§ 823(b), 824(a)(4).

[11] 21 U.S.C. §§ 823(b) and (f).

substances…"[12] and, in turn, the DEA has promulgated regulations that impose certain security requirements for all registrants.[13] For example, 21 C.F.R. § 1301.71(a) states that "all applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances." Further, as provided in 21 C.F.R. 1301.74(b):

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

This regulation has been in place since 1971 and remains unchanged to this day.[14]

By way of its Diversion Control Division, the DEA seeks to prevent, detect, and investigate the redirection of controlled pharmaceuticals and listed chemicals to illegitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs. To that end:

> The mission of the Drug Enforcement Administration (DEA) is to enforce the controlled substances laws and regulations of the United States and bring to the criminal and civil justice system of the United States, or any other competent jurisdiction, those organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for ***illicit traffic*** in the United States; and to recommend and support non-enforcement programs aimed at reducing the availability of ***illicit controlled substances*** on the domestic and international markets.[15]

[12] 21 U.S.C. § 821.

[13] 21 C.F.R. §§ 1301.71-1301.77 (the "Regulations").

[14] The recent decision *U.S. v. Wal-Mart, Inc.*, 2024 WL 1051017 (D. Del. March 11, 2024) held that the CSA did not impose an obligation to report suspicious orders to the DEA until Congress amended the CSA in 2018 through the passage of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. No. 115-271, § 832(a), 132 Stat. 3894, 3956 (2018); 21 U.S.C. §§ 832(a)(1), (3).

[15] Drug Enforcement Administration Mission and Functions Manual (2012) https://www.justice.gov/archive/jmd/mps/2012/manual/dea.htm#:~:text=The%20mission%20of%20the%20DEA,in%20the%20growing%2C%20manufacture%2C%20or.

This statement is the guiding principle for every action taken by the DEA and reflects the fact that the DEA is focused on the diversion of controlled substances ***outside*** of the closed system of distribution rather than on distribution to pharmacies dispensing to patients pursuant to legitimate prescriptions.

B. Pursuant to 1301.71(b), the DEA Requires "Substantial Compliance" with the CSA Regulations

The CSA requires substantial compliance with the Regulations as opposed to perfect compliance. Specifically, satisfaction of the standards set forth in §§ 1301.72-1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant.[16] This assessment is based on the evaluation of a number of factors, including, but not limited to, the type of activity conducted by the registrant. Based on my review of the DEA Reports of Investigation related to the Publix pharmacy warehouse, the Publix ARCOS data, and the Publix dispensing data, as discussed below, it is my opinion that Publix was in compliance with the CSA from 2006 to the present.

C. The DEA does not endorse any specific SOM system and instead Registrants have discretion to develop their system based on their individual operations and needs.

Despite imposing an obligation to identify and report suspicious orders in the CSA, the DEA has provided limited, if any, guidance regarding (1) the specific requirements of a SOM system or process; and (2) the criteria that identify or constitute suspicious orders. Other than the broad and ambiguous directive to identify "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency," [17] the Regulations do not provide any guidance on how to apply these criteria and instead are silent as to what registrants must do to

[16] 21 C.F.R § 1301.71(b).

[17] 21 C.F.R. 1301.74(b).

ensure that their "systems" are compliant. Accordingly, the DEA does not endorse any specific SOM system or process and, instead, the design and implementation of a SOM system is based on each registrant's business model and, therefore, differs from registrant to registrant. Because there is not a "one size fits all" approach to SOM systems, the DEA remains focused on its primary goal of preventing diversion.

While the DEA did prepare guidance letters to the industry regarding general expectations, it has not sought to modify the Regulations nor has it set forth absolute requirements for SOM systems.[18] This lack of guidance has created uncertainty among registrants regarding what is expected under the Regulations and, as a result, registrants have proactively sought direction from the DEA regarding the need for greater detail in the Regulations.

In 2015, the U.S. Government Accountability Office ("GAO") issued a report wherein distributors noted that "…vague mandates of 'knowing your customers' needs to be clarified as it [cannot] be found within the CFR or guidance [letters]…."[19] The GAO's report noted that distributors also remarked that:

> [I]t would be very helpful if DEA provided further clarification regarding responsibilities associated with 21 CFR 1301.74(b), [Suspicious] Order Monitoring and applicable guidance letters. DEA has pursued aggressive enforcement of these regulations, but [does] not provide a clear roadmap for what is expected to be compliant.[20]

In its report, the GAO recommended that DEA solicit input from distributors, or associations representing distributors, and develop additional guidance regarding a distributor's roles and responsibilities in suspicious order monitoring and reporting.[21]

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[18] *See* Dear Registrant Letters *infra* n. 24, 27.

[19] U.S. Government Accountability Office, GAO-15-471, *More DEA Information About Registrant's Controlled Substance Roles Could Improve Their Understanding and Help Ensure Access* (2015) at p. 26.

[20] *Id.*

[21] *Id.* at p. 44.

Although registrants had received informal guidance from different sources prior to the GAO's Report, such guidance is not binding in the way that formal amendments to the Regulations are when submitted through the formal rulemaking process. In my opinion, the absence of comprehensive guidance in the Regulations has made an already difficult task even more challenging as registrants are forced to balance their obligations under the CSA with their obligation to patients who receive controlled substances for their legitimate medical needs. Further, without such written guidance or clarification from the DEA, distributors had to rely heavily on the words (or lack of words) and actions (or lack of action) from the DEA through direct interactions via inspections and licensing procedures to understand if the distributor is viewed as in compliance or not. While Publix has been diligent in developing a SOM system that meets the needs of its self-distribution model and maintains effective controls against diversion, the following section explores the historical guidance DEA has provided to registrants.

D. DEA's Historic Guidance to Registrants

The primary reason for the implementation of a SOM system is to detect and prevent diversion at the retail dispensing level through the filling of illegitimate prescriptions. Because DEA leaves to the registrant the discretion to develop the scope, scale and parameters of its SOM system, it is reasonable to take into account the inherent differences between a self-distributor and a wholesale distributor. Specifically, a wholesale distributor: (1) has a sales teams that calls on potential new pharmacy customers; (2) has no direct line of site into a pharmacy customer's operations & dispensing practices; and (3) sells to all types of customers including internet pharmacies, hospitals, dentists, medical practices, and independent retail pharmacies. Conversely, a self-distributor such as Publix (1) does not have a sales team that solicits its pharmacies; (2) has real-time, continuous line of site into its pharmacy operations and dispensing; and (3) only self-

distributes to its own pharmacies. The DEA recognizes that a wholesale distributor and a self-distributor such as Publix can have different SOM systems based, in part, on these differences. [22]

In the context of self-distribution, SOM is another control designed to detect and prevent the filling of illegitimate prescriptions at the retail level and in that sense is a "back up" control. Whether called SOM explicitly or not, activities designed to detect and prevent retail level diversion – such as the filling of illegitimate prescriptions - reinforce and support SOM. In the context of SOM and detecting potentially suspicious orders, Mr. Rannazzisi recognizes that Publix, as a self-distributor was engaged in various activities that furthered the SOM's goal of detecting diversion at the retail level.[23] Set against this backdrop, it is important to understand the DEA's guidance to the registrant community.

1. The 2006 and 2007 "Dear Registrant" Letters.

In September 27, 2006, Mr. Rannazzisi in his capacity as the DEA Deputy Assistant Administrator in the Office of Diversion Control issued the first in a series of "Dear Registrant Letters" as part of effort to clarify what was required of registrants (the "2006 Dear Registrant Letter").[24] In such letter, the DEA also identified certain conduct for registrants that may indicate pharmacies were dispensing controlled substances for illegitimate purposes:

> 1. Ordering excessive quantities of a limited variety of controlled substances (e.g., ordering only phentermine, hydrocodone, and alprazolam) while ordering few, if any, other drugs.
>
> 2. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered

[22] Dep. Tr. M. Mapes (July 11, 2019) ("Q: And would you agree that it could be reasonable for a retail chain pharmacy like Walmart to not have to include all of the compliance measures in its SOM systems that might be necessary for a distributor who distributes controlled substances to customers that the distributor does not own?....A: Yes, I agree there could be differences between the systems for those two organizations.").
[23] Dep. Tr. J. Rannazzisi 339:2-343:11 (May 30, 2024).

[24] Dear Registrant Letter from J. Rannazzisi dated September 27, 2006.

> 3. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs.
>
> 4. Ordering the same controlled substance from multiple distributors.[25]

The DEA also identified questions that a distributor may wish to ask its customers when evaluating whether an order was suspicious. Importantly, the DEA recognized that "the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion."[26]

The DEA issued another Dear Registrant Letter, also authored by Mr. Rannazzisi, to registrants on December 27, 2007 (the "2007 Dear Registrant Letter").[27] The 2007 Dear Registrant Letter intended to reiterate the obligations under the CSA noting that:

> The regulation clearly indicates that ***it is the sole responsibility of the registrant to design and operate such a system***. ***Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders***.[28]

Mr. Rannazzisi also directed registrants to the then-recent final order in *Southwood Pharmaceuticals* for additional guidance on the criteria to use when determining whether an order is suspicious and the obligation to maintain effective controls against diversion.[29] While perhaps helpful to some registrants, there are absolutely no similarities in the conduct of third-party distributors like Southwood and Publix. As such, the final order's value in analyzing the effectiveness of Publix's SOM system is to demonstrate how far removed Publix was from Mr. Rannazzisi's example of what constitutes improper conduct. [30] In the following years, the DEA's

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[25] *Id*. at p. 3.

[26] *Id*. at p. 2.

[27] Dear Registrant Letter from J. Rannazzisi dated December 27, 2007.

[28] *Id*. (emphasis added).

[29] *Southwood Pharmaceuticals, Inc., Revocation of Registration*, 72 Fed. Reg. 36487 (July 3, 2007).

[30] *See infra*. Publix, on the other hand, has never received a similar (or any) warning from the DEA and has only ever self-distributed controlled substances in numbers much smaller as compared to those distributed by Southwood.

vigilance has resulted in the imposition of significant fines and the revocation of registrations for distributors. Publix has never been subject to any such penalty.

2. DEA Considers Amendments to Regulations in 2020.

On November 2, 2020, the DEA issued a notice of rulemaking proposing "to clarify the procedures a registrant must follow for orders received under suspicious circumstances (ORUSCs)."[31] The proposal specifically provided that:

> Upon receipt of an ORUSC, registrants authorized to distribute controlled substances would have a choice of proceeding under one of two options (the "two option framework"). In addition, these registrants would be required to submit all suspicious order reports to a DEA centralized database, and keep records pertaining to suspicious orders and ORUSCs.[32]

The first option under this proposal requires the distributor to file the suspicious order report through the DEA's centralized database, stop the shipment, and maintain all due diligence. Under the second option, the distributor may conduct due diligence in order to "dispel each suspicious circumstance surrounding the ORUSC within seven calendar days"[33] and, if they dispel each suspicious circumstance, the distributor may then ship the order while still maintaining a record of the due diligence. If the suspicious circumstance is not dispelled, the distributor must file a suspicious order report through the DEA centralized database and cancel the order. Notably absent from the proposed amendments to the Regulations is any reference to a distributor's SOM system, which suggests that the DEA still maintains its position that it will not outline the specific parameters of, or endorse a particular approach to creating a SOM system. Instead, each distributor remains solely responsible for the design of its own program. The proposed rule provided an

[31] Notice of Proposed Rulemaking to Suspicious Orders of Controlled Substance, 85 Fed. Reg. 69,282 (Nov. 2, 2020).

[32] *Id.*

[33] *Id.*

opportunity for the public, including distributors, to submit comments to DEA. The DEA has yet to implement the new rule, allowing ambiguity and confusion to persist.[34]

As seen as recently as January 20, 2023, the DEA continues to decline to provide any guidance on whether registrants should limit the amount of controlled substances to any pharmacy.[35] In a guidance document, the DEA concluded that "neither the CSA nor DEA regulations establish quantitative thresholds or limits on the amounts of controlled substances, including for MOUD [36], that DEA registrants may order or dispense, nor do they require registrants to set such thresholds or limits."[37] The DEA's historical and continued reluctance to provide formal guidance has created confusion among registrants regarding what steps need to be taken to comply with their obligations to provide effective controls against diversion.

Nonetheless, Publix has continued to operate and adjust its practices as a self-distributor under the limited guidance of the DEA, but, in any event, at all times consistent with suggestions or feedback received in direct interactions with DEA diversion investigators responsible for inspecting Publix's pharmacy warehouse and its SOM practices. In my opinion, Publix acted reasonably in relying on its interactions with the DEA and state regulators, as well as law enforcement and licensing bodies, as a means to confirm its understanding that its SOM system and programs, along with all of its anti-diversion processes and procedures, were appropriate and acceptable methods designed to meet the goal of SOM to prevent diversion of opioids.

[34] Notice of Proposed Rulemaking to Suspicious Orders of Controlled Substance, 85 Fed. Reg. 69,282 (Nov. 2, 2020).

[35] Drug Enforcement Administration Diversion Control Division Guidance Document EO-DEA258, DEA-DC-065 (Jan. 20, 2023), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-065)(EO-DEA258)_Q_A_SOR_and_Thresholds_(Final).pdf#search=DEA-DC-065.

[36] MOUD stands for Medication for Opioid Use Disorder.

[37] DEA Guidance Document EO-DEA258, DEA-DC-065, *supra* n. 35.

Without considering the above and weighing the potential shortcomings of the limited guidance provided by DEA, Mr. Rannazzisi's conclusion that Publix's allegedly deficient SOM system was a substantial cause of the opioid epidemic is unfounded as it based on an incomplete analysis. Critically, Mr. Rannazzisi cannot establish that (1) Publix failed to identify any suspicious order; or (2) there was any actual diversion occurring at any Publix pharmacy, let alone one located in Cobb County, Georgia, that resulted from an ineffective SOM system.

E. DEA's Consistent Mantra Has Been for Distributors Not to Sell Opioids to Outliers

As mentioned above briefly regarding *Southwood*, the DEA's administrative actions against other registrants offer some insight into the level and scope of misconduct that the DEA believes constitutes diversion. In my experience, the primary contributor to the increase in diversion of opioids was the rise of pill mills – something with which Mr. Rannazzisi appears to agree.[38] As a DEA supervisor responsible for over 8,000 DEA registrants in 67 Georgia counties, my Diversion Investigators and Investigative Assistant were challenged to keep up with the spread of these rogue clinics.

Rogue pain clinics were normally operated by non-DEA registrants who hired practitioners to either write prescriptions or directly dispense controlled substances to the patients for no legitimate medical purpose.[39] The patients, mostly drug seekers, would travel in large groups from long distances with large amounts of cash (as most of the rogue pain clinics, in my experience, only accepted cash). Those patients that received prescriptions headed to pharmacies in the area

[38] Dep. Tr. J. Rannazzisi 200:6-23 (Apr. 26, 2019) ("Our resources shifted [in 2008] to rogue pain clinics because the Internet pharmacy cases pretty much went away. There was no more domestic brick and mortar pharmacies that were fulfilling Internet orders because Ryan [Haight] pretty much eliminated them, so the resources were shifted over to rogue pain clinics.").

[39] *DEA Deputy Admin'r Rannazzisi's Testimony before the House of Representatives Comm. on Energy and Commerce*, Apr. 29, 2014 ("I think that if you are talking about 99.5 percent of the prescribers, no, they are not overprescribing, but our focus is in rogue pain clinics and rogue doctors who are overprescribing.").

or those on the way home that were along the interstate that they knew would fill the prescriptions. These pharmacies filled large numbers of hydrocodone or oxycodone prescriptions along with a benzodiazepine like Xanax and a muscle relaxer such as Soma without verifying the legitimacy and purpose of the prescription. While some pharmacists would speak with the prescribing practitioner in these instances, others turned a blind eye to the prescriber's justification. Publix pharmacies were never considered to be one of these rogue pharmacies by me or my DEA colleagues in the field.

The most direct way to identify a bad pharmacy involves an analysis of the amount and types (including strength) of drugs purchased relative to national or state averages as well as an examination of the ratio of controlled substances prescriptions to all prescriptions filled by that pharmacy. Ideally, a pharmacy should dispense a wide variety of drugs, and controlled substances would comprise only a reasonable part of that dispensing. The DEA has historically suggested that an 80/20 ratio is reasonable in that 80% of the dispensed medications are not controlled substances as compared to 20% of the dispensed medications being controlled substances.[40]

One such example of a distributor supplying rogue pharmacies with controlled substances can be seen in the *Southwood* case.[41] In *Southwood*, the DEA sought to revoke the registration of a distributor that was shipping massive amounts of hydrocodone to its internet pharmacy customers, which were dispensing hydrocodone subject to illegal prescriptions. Over an 8.5-month period, one customer ordered 8,671,000 dosages units of hydrocodone for a ***monthly*** average of

[40] Dep. Tr. J. Rannazzisi at 215:13-215:17 (April 26, 2019) ("High volume, high ratio, controlled substance to non-controlled substance is an indicator of a potential problem, yes."); Dep. Tr. K. Wright at 260:13 -261:1 (Feb. 28, 2019) ("Q: Is it accurate to say that you knew that it was common for legitimate pharmacies to have a ratio of approximately 20 percent of controlled to 80 percent noncontrolled? A. In that area, yes. Q: Okay. And higher percentages of controlled drugs could be reasonable at times, right? A: Yes. For example, pharmacies located right next to a cancer clinic or something like that.").

[41] *Southwood Pharmaceuticals, Inc., Revocation of Registration,* 72 Fed. Reg. 36487 (July 3, 2007).

1,011,882 dosage units.[42] In some instances, these pharmacies were purchasing only controlled substances from Southwood and nothing else. Even after Southwood learned that its customers were operating in an illegal manner, Southwood continued to supply excessive amounts of hydrocodone to its customers. In reaching its decision to revoke Southwood's registration, the DEA Deputy Administrator held:

> As stated above, these websites and the pharmacies that fill the prescriptions issued by them, are nothing more than drug pushers operating under the patina of legitimate authority. Cutting off the supply sources of these pushers is of critical importance in protecting the American people from this extraordinary threat to public health and safety. In accomplishing this objective, this Agency cannot do it all itself. It must rely on registrants to fulfill their obligation under the Act to ensure ***that they do not supply controlled substances to entities which act as pushers***.[43]

Put simply, the conduct in *Southwood* is what the failure to maintain effective controls against diversion looks like.

The DEA's administrative action against Masters Pharmaceuticals yielded similar results based upon similar egregious conduct distributing to similar types of outlier pharmacies. [44] In *Masters Pharmaceuticals*, the DEA sought the revocation of Masters' certificate of registration. In addition to the overall volume, the DEA Administrator considered a number of other data-driven criteria when assessing each pharmacy's ordering and dispensing practices. The DEA identified a number of customers that were dispensing controlled substances at an extremely high rate relative to all prescriptions filled. The ratio of controlled substance prescriptions to all prescriptions was in excess of 60%. In another example, oxycodone 15mg and oxycodone 30mg collectively accounted for more than 70% of all prescriptions filled by the pharmacy. The DEA also identified

[42] *Id*. at 36488. In stark contrast, the Publix Cobb County pharmacies on average were ***annually*** dispensing 98,199 total dosage units of 14 different opioids between 2006 and 2019. *See* Section VII(A) *infra*.

[43] *Id*. at 36504 (emphasis added).

[44] *Masters Pharmaceuticals, Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017).

one customer where 85% of the controlled substance prescriptions were paid for in cash. Ultimately, the distributor must evaluate whether it is shipping controlled substances to a "bona fide retail pharmacy" as opposed to those pharmacies that "might be involved in illegal diversion."[45] The pharmacy customers in *Masters* were not operating as a "bona fide retail pharmacy."[46] Publix's pharmacies and self-distribution practices bear no resemblance to the conduct at issue in either *Southwood* or *Masters Pharmaceuticals.* Mr. Rannazzisi's report neither includes nor references any data analysis suggesting otherwise nor could it have as demonstrated by the data analyses performed for this litigation by Publix's statistics and data expert Candice Rosevear, some of which are referenced further into this report.

1. DEA Did Not Give SOM Guidance to Distributors Because It Was Focused On the Primary Goal of Preventing Diversion.

Pursuant to its Mission Statement, the DEA has always remained focused on a single, overarching goal – preventing diversion. The DEA does not tell distributors how to develop their SOM system and has reiterated this message to distributors over the last 20 years. In fact, the DEA repeatedly told distributors that it is solely their responsibility to develop such a system.[47] Each distributor operates in a different fashion and services a different customer base. For example, it would be unrealistic to expect that a large wholesale distributor with a national customer base would use the same SOM system as a small, regional wholesale distributor focused on independent retail pharmacy customers. Similarly, it would be difficult to see how either of those systems would be optimal for a self-distributor such as Publix. Accordingly, the key requirement for an optimal

[45] *Masters*, 861 F.3d at 220.

[46] *Id*.

[47] 2006 and 2007 Dear Registrant Letters from J. Rannazzisi, *infra* n. 24, 27; *see also* Dep. Tr. of K. Wright 344:25-35:17 (March 4, 2019) ("Q. And it says: "Accordingly, DEA does not approve or otherwise endorse any specific system for reporting suspicious orders." Is that consistent with the messaging that you had in your distributor initiative briefings? …A: Yes, sir. It was.").

suspicious order monitoring system is that each distributor must ultimately design a system that contributes to its overall efforts to prevent diversion.

The Publix SOM program and its pharmacy operations were clearly effective in preventing diversion and, as discussed in greater detail below, this is supported by both the ARCOS data and Publix dispensing data. Publix's self-distribution trends (and the ultimate dispensing of controlled substances) reveal that the volume of oxycodone and hydrocodone shipped to its pharmacies was well below county, state and national averages. Moreover, controlled substances comprised a reasonable and unremarkable part of the overall dispensing at each of its pharmacy locations in Cobb County. Publix's dispensing also skews toward lower dosage opioids especially when compared to other retail and chain pharmacies in Cobb County and nationally.[48] Mr. Rannazzisi's expert report ultimately turns a blind eye to this data.[49] Mr. Rannazzisi does not and cannot offer a credible assessment of Publix's efforts in creating and adjusting its SOM system over time without any understanding of what was *actually* being shipped to and dispensed by Publix pharmacies. To the contrary, Mr. Rannazzisi's report elevates form over function, and any claimed "deficiencies" simply ignore the fact that Publix was effective and successful in preventing diversion. At its core, Mr. Rannazzisi's expert report compiled a list of theoretical administrative shortfalls and completely avoided the opportunity to conduct any type of reliable data analysis from which he could reasonably conclude that Publix's SOM practices eventually resulted in the filling of illegitimate prescriptions.

[48] *See* Section VII(D) *infra*.

[49] It is my understanding that previous DEA experts working for plaintiffs, including Mr. Rannazzisi, have provided some degree of data analysis to support their assessment of a particular SOM system, yet no such analysis has been done in this case.

2. DEA Has Never Required Documentation of Due Diligence.

Throughout his report, Mr. Rannazzisi opines that distributors were required to (1) document all due diligence related to any potentially suspicious order and (2) maintain those records indefinitely.[50] Admittedly, the Regulations require that registrants keep "inventory and other records" for "at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration."[51] However, the CSA and the Regulations are silent as to the retention of due diligence materials.[52] The DEA has never modified or amended the CSA and its Regulations to require that registrants maintain "due diligence" files or suspicious order reports.[53] Mr. Rannazzisi attempts to impose a requirement where no such requirement has ever existed.

Moreover, Mr. Rannazzisi's contention is undermined by the DEA's recent proposal to modify the Regulations regarding the handling of suspicious orders which, if issued, will only now include, for the first time ever, an explicit requirement to keep "all records pertaining to suspicious orders and Orders Received Under Suspicious Circumstances (ORUSC)."[54] This proposed rule would require the distributor to maintain all records regardless of whether the order was ultimately confirmed as suspicious. In simplest terms, there would be no need for an amendment if the Regulations already imposed the obligation Mr. Rannazzisi claims exists for distributors.

[50] Expert Report of J. Rannazzisi at pp. 10, 15 (January 24, 2024).

[51] 21 C.F.R. § 1304.04.

[52] Dep. Tr. K. Wright 143:2-12 (Feb. 28, 2019) ("Q: And the exercise that the registrant goes through to do some due diligence to really bear out whether the order is, in fact, truly a suspicious order or not, that due diligence exercise, is there a regulatory requirement to document that due diligence? …A: No").

[53] 21 U.S.C. §§ 801 et. seq.; 21 C.F.R. §§ 1301.71 et seq.

[54] Notice of Proposed Rulemaking to Suspicious Orders of Controlled Substance, 85 Fed. Reg. 69,282 (Nov. 2, 2020).

3. DEA Has Never Indicated That Registrants Must Have SOM Specific Analysts.

In his report, Mr. Rannazzisi also implies that Publix should have had specific employees working as "diversion analysts" from the time that Publix first self-distributed controlled substances.[55] In 2019, Publix did create a position with the title "diversion analyst" as part of the further development of its SOM program and the centralization of certain SOM activities, but it was not the first time that Publix had an employee reviewing flagged orders, the functional equivalent. As set forth in Section V, Publix had Pharmacy Supervisors review and analyze flagged orders prior to the creation of the diversion analyst position. Like many other claims in Mr. Rannazzisi's report, the CSA and the Regulations do not impose a responsibility on registrants to have the specific position of "diversion analyst."[56]

4. DEA's Focus on Diversion Was a Focus on Outliers and Specific Controlled Substances.

As reflected in both *Southwood* and *Masters Pharmaceuticals,* the DEA's has remained focused on pharmacies that were ordering controlled substances in a manner well outside the range of what would be expected from a full-service pharmacy. DEA expected distributors to monitor orders to pharmacy customers to ensure none of the customers were acting as an outlier rogue pharmacy/drug pusher. Based on the average pharmacy's dispensing, DEA was not concerned with trying to prohibit distributors from distributing to the average pharmacy. Rather, as noted, DEA wanted distributors to focus on outlier customers.[57] Based on my experience, the DEA was also primarily focused specifically on the diversion of hydrocodone and oxycodone. Opioids such as

[55] Expert Report of J. Rannazzisi at p. 72 (January 24, 2024).

[56] 21 U.S.C. §§ 801 et. seq.; 21 C.F.R. §§ 1301.71 et seq.

[57] Dep. Tr. J. Rannazzisi 340:2-8 (May 30, 2024) ("Q: Would you agree that a system that compares pharmacies against their peers and against all of a chain's pharmacies to identify outliers can be effective for detecting pharmacies with suspicious ordering patterns? A: Again, if you're doing all three, yes, it can.").

oxycodone and hydrocodone have a wide range of legitimate medical uses and are an expected and appropriate part of an average pharmacy's dispensing.

With these parameters in mind, Publix was successful in its own efforts to distribute consistent and appropriate volumes of both oxycodone and hydrocodone to its pharmacies. As discussed in Section VII, Publix pharmacies do not qualify as outliers in my opinion, and the distribution (and dispensing) of controlled substances was always well below the 80:20 ratio relied upon by the DEA to identify pharmacies not engaged in misconduct leading to diversion.

V. Publix Distribution System and Compliance with the CSA

A. Overview of Publix Operations

Publix currently operates 1,376 stores located in Alabama, Florida, Georgia, Kentucky, North Carolina, South Carolina, Tennessee and Virginia[58] and, between 2006 and 2020, Publix operated 26 pharmacies in Cobb County.[59]

Beginning in 2005, Publix self-distributed Schedule III through Schedule V controlled substances to its pharmacies from its Sand Lake Warehouse located on the Publix Distribution Center Complex at 1950 Sand Lake Road in Orlando, Florida. From 2005 until the Sand Lake warehouse was closed in 2016, Publix self-distributed only Schedule III through V controlled substances, including codeine, buprenorphine and hydrocodone combination products. When hydrocodone combination products were rescheduled from Schedule III to Schedule II in October 2014,[60] Publix ceased self-distributing those products until October 2016 when it opened its Rocket Court Warehouse located at 10400 Rocket Ct., Orlando, Florida 32824. In other words,

[58] http://corporate.publix.com/about-publix/company-overview/facts-figures.

[59] PUBLIX-MDLT8-00000002.

[60] DEA, *DEA to Publish Final Rule Rescheduling Hydrocodone Containing Products* (Aug. 21, 2014) https://www.dea.gov/press-releases/2014/08/21/dea-publish-final-rule-rescheduling-hydrocodone-combination-products.

Publix did not self-distribute any Schedule II controlled substance (including oxycodone 15mg and oxycodone 30 mg, the most highly abused controlled substances during the opioid crisis) until October 2016 nor did Publix self-distribute any hydrocodone or oxycodone (or any other Schedule II controlled substance) between October 2014 and October 2016. [61] Additionally, as a self-distributor Publix transferred controlled substances within a closed system from its DEA-registered centralized warehouse only to its own pharmacies. Publix never distributed to any independent pharmacies, chain pharmacies, internet pharmacies, or other dispensers such as hospitals , physicians, medical practices, and long-term care facilities.

Between 2006 and 2021, Publix warehouses and its SOM system were regularly subject to extensive and thorough DEA inspections. All such investigations were closed without DEA taking any adverse action against Publix, which included action related to Publix's SOM system. The lack of adverse action reinforces that Publix employed a multifaceted approach to meeting and exceeding its obligations under the CSA. Publix's SOM system was more than just the application of a threshold or an algorithm.[62] Publix also focused on hiring quality pharmacists and managers and gathering critical information regarding inventory and dispensing trends. And, as a self-distributor, orders of all drugs were subject to multiple levels of review before they left the warehouse, but Publix was also able to maintain control over orders even after they were shipped. The development of a comprehensive SOM system takes time and effort. In my opinion, Publix's strong commitment over time to ensure that it remains in compliance with its obligations under the CSA and the Regulations was successful.

[61] Dep. Tr. C. Hewell 152:14-18 (Nov. 4, 2022).

[62] Dep. Tr. J. Rannazzisi 339:2-339:22 (May 30, 2024).

B. The Evolution of the Publix SOM System

1. Publix Items Management System/Ship Max (2006 – 2012)

Publix opened its Sand Lake warehouse in 2005.[63] As part of that process, Publix implemented the Orlando Pharmacy Warehouse Security Plan (the "Security Plan").[64] The Security Plan covered a wide array of topics including, but not limited to, security staffing, perimeter security, access control, facility operation, and facility operation.[65] Designated storage areas within the warehouse, known as cages, were equipped with enhanced security. These areas are constructed of wire mesh walls, with self-closing doors, access control and alarm devices. Access to caged areas is restricted to only those associates who perform or supervise work functions within those areas.[66] Additionally, the Pharmacy Department Manager had to "ensure that inventory losses are reported to the appropriate governmental agencies in the manner and timeframe required."[67] All of these are crucial aspects of complying with the obligations imposed by the CSA and the Regulations.

On August 9, 2005, Publix implemented the Orlando Pharmacy Warehouse Standard Operating Procedures.[68] The Pharmacy Receiver was trained in pharmaceutical receiving and reviewed all inbound shipments, including controlled substances and the receiving of product into the facility.[69] Before the Sand Lake warehouse opened, Publix had implemented its Pharmacy

[63] Dep. Tr. C. Hewell 150:22-151:2 (Nov. 4, 2022).

[64] PUBLIX-MDLT8-00058213-00058277.

[65] *Id.*

[66] *Id.*

[67] *Id.*

[68] PUBLIX-MDLT8-00058108-00058142.

[69] *Id.*

R&P Guide, which guided the behavior of its pharmacists. [70] Specifically, Publix pharmacists were the only employees authorized to order and receive C-II controlled substances, and they were required to complete a monthly CII physical inventory count between the first and the fifth of each month.[71] The pharmacists were also required to report any theft or loss of a controlled substance to both the DEA and the Publix Corporate Loss Prevention Department.[72]

The Publix Inventory Management System ("PIMS") was the earliest formal threshold-based component of the Publix SOM system.[73] PIMS was operational from 2006 through 2012.[74] During this timeframe, Publix was only self-distributing Schedule III through Schedule V controlled substances.[75] The PIMS system imposed conservative limits on controlled substances and would automatically cut orders in excess of the threshold for the specific pharmacy.[76] These thresholds were the same for all Publix stores, and pharmacy supervisors were responsible for evaluating any request to modify a threshold changes.[77] Though it does not require use of thresholds, DEA recognizes them as a valid SOM control and leaves to the registrant the decision where they should be set.[78] In the case of Publix, the use of "ship max" thresholds limited the quantity and frequency with which Publix's pharmacies could order controlled substances and were set conservatively to reflect the historical utilization pattern of Publix's pharmacies, overall.

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[70] Pharmacy R&P Guide, Chapter 14: Ordering Supplies and Product at PUBLIX-MDLT8-00011097-00011147.

[71] *Id.*

[72] *Id.*

[73] Dep. Tr. C. Hewell 139:13-140:5 (Nov. 4, 2022).

[74] Dep. Tr. C. Hewell 180:6-9. (Nov. 4, 2022).

[75] Dep. Tr. C. Hewell 139:8-12. (Nov. 4, 2022).

[76] Dep. Tr. C. Hewell Tr. 147:16-148:12 (Nov. 4, 2022); Dep. Tr. of Publix 30(b)(6) Representative Regarding Distribution Topics 58:3-19. (July 25, 2023).

[77] Dep. Tr. of Publix 30(b)(6) Representative Regarding Distribution Topics 58:3-19; 66:13-18. (July 25, 2023).

[78] *Supra* n. 35.

If an order was flagged by the PIMS system, both the pharmacy manger and the pharmacy supervisor for the store at issue received an email stating as such.[79] They would then review the flagged order to determine whether it was suspicious by reviewing relevant information, including the pharmacy's dispensing history, monthly trend reports, and manual inventory adjustment reports.[80] Such review may also include a determination on a Threshold Change Request made by a pharmacist.[81] During this timeframe, Publix would also conduct quarterly compliance meetings to discuss ordering trends, controlled substance distribution and training.[82] Publix also worked to ensure that it had additional processes in place to evaluate if a Publix pharmacy engaged in a pattern of ordering more than it was dispensing.[83]

2. Publix Continued to Improve Its SOM System Between 2012 and 2016

In October 2012, the PIMS system was enhanced to allow Publix to set individual thresholds for each store. [84] Specifically, Publix expanded the auditing functionality of the PIMS system to include:

> 1. Monthly controlled substance thresholds by drug molecule for each pharmacy. A drug molecule is defined by the controlled active ingredient and dosage form. For example, the 'Hydrocodone CT' molecule will include all hydrocodone capsules and tablets, while the 'Hydrocodone ML' will include all hydrocodone liquid formulations. Thresholds are determined by an analysis of a pharmacy's historical purchasing patterns and dispensing trends;

[79] Dep. Tr. of Publix 30(b)(6) Representative Regarding Distribution Topics 61:14-22. (July 25, 2023).

[80] Dep. Tr. of Publix 30(b)(6) Representative Regarding Distribution Topics 61:23-63:4; 64:6-65:12 (July 25, 2023).

[81] *See, e.g.*, PUBLIX-MDLT8-00065743 (2011 Email from a Cobb County Area Supervisor regarding consideration and submission of threshold change requests); PUBLIX-MDLT8-00066239 (2013 Threshold Change Request from Pharmacist in Cobb County).

[82] Dep. Tr. F. Ottolino 100:12-24; 114:2-116:8; 159:14-21 (Dec. 6, 2022).

[83] Dep. Tr. C. Hewell 140:17-141:2 (Nov. 4, 2022). To the extent that Publix stores were ordering controlled substances from any third-party wholesale distributors, those orders would not implicate any of Publix's obligations as a ***distributor*** under the CSA. Those orders would be subject to review and reporting, if necessary, by the third-party wholesale distributor.

[84] Dep. Tr. of Publix 30(b)(6) Representative Regarding Distribution Topics 59:12-20 (July 25, 2023).

> 2. The ability to monitor accumulated monthly units purchased for all controlled substances;
>
> 3. Notifications to pharmacies that are close to reaching their controlled substance threshold will be notified by an automated "Order Quantity WARNING for Controlled Substances" email;
>
> 4. Notifications to pharmacies that reach the controlled substance threshold will be notified by an automated "Order Quantity VIOLATION for Controlled Substances" email. No additional units will be shipped to your pharmacy for the remainder of the month without further action.; and
>
> 5. A procedure for pharmacies to obtain a higher monthly allocation. Each pharmacy must fill out the Pharmacy Controlled Substance Threshold Request Form located on the Pharmacy portal in the Web Form section and submit it to the Pharmacy Supervisor and Pharmacy Operations Manager for approval.[85]

As a result, pharmacy managers and pharmacy supervisors would receive a notification of any flagged orders and the pharmacy supervisors would then evaluate them.[86] On December 13, 2012, these changes were formally incorporated into the Pharmacy Warehouse Controlled Substance Auditing Policy and Program.[87] In 2012, Publix also began using the Controlled Substance Ordering System ("CSOS") system to submit CII orders, which provided another level of review for all CII orders, which at the time would be fulfilled only by third-party, wholesale distributors independent of Publix.[88] The new PIMS system thus continued to use "ship max" thresholds limiting the quantity and frequency with which Publix's pharmacies could order controlled substances, but were now set to reflect the historical utilization pattern of Publix's pharmacies, individually. Enhancements to the threshold-setting process and the other expanded improvements

[85] PUBLIX-MDLT8-00118720.

[86] Dep. Tr. of Publix 30(b)(6) Representative Regarding Distribution Topics 79:1-9 (July 25, 2023).

[87] PUBLIX-MDLT8-00098667.

[88] PUBLIX-MDLT8-00120562-00120566; Dep. Tr. C. Hewell 195:10-12; 212:6-13; 212:22-24 (Nov. 4, 2022).

introduced in this period reflect Publix's ongoing commitment to improving their overall approach to suspicious order monitoring and maintaining effective controls against diversion.

Between 2012 and 2016, Pharmacy Supervisors were responsible for reviewing any orders of interest flagged by the PIMS system.[89] The Pharmacy Supervisors were responsible for determining whether the order was suspicious or whether the store's threshold should be adjusted.[90] In order to complete their due diligence, the Pharmacy Supervisors would consider several different data sources, including but not limited to: (1) the dispensing history of the pharmacy; (2) monthly CII Pull Reports[91] (including the percentage of controlled prescriptions, patients paying cash, total prescription count, and prescription data for specific controlled substances including oxycodone and hydrocodone products); and (3) manual inventory and adjustment reports.[92] This information would allow for an assessment of the quantity, pattern and frequency with which the store ordered, received, and dispensed controlled substances. Even though these orders of interest were subject to review, any item that was flagged was automatically cut from the order, and there was no override to add the flagged item to the order.[93] Consequently, without regard to the ultimate status of that line item in the order as suspicious or not, the flagged line item was not fulfilled by Publix's pharmacy warehouse. The Pharmacy Operations Managers,

[89] Dep. Tr. C. Hewell 139:12-17 (Nov. 4, 2022).

[90] Dep. Tr. of Publix 30(b)(6) Representative Regarding Distribution Topics 62:24-63:4 (July 25, 2023); Dep. Tr. L. Jacobsen 318:23-321:9 (Nov. 8, 2022).

[91] Publix included its dispensing of CII controlled substances in these reports even though it did not start distributing them until October 2016.

[92] Dep. Tr. L. Burckhalter 87:4-89:9 (Aug. 11, 2023); Dep. Tr. of Publix 30(b)(6) Representative Regarding Distribution Topics 65:9-66:4 (July 25, 2023); Dep. Tr. F. Ottolino 83:11-87:19, 231:5-25 (Dec. 6, 2022); Dep. Tr. L. Jacobsen 115:22-116:24 (Nov. 8, 2022).

[93] Dep. Tr. C. Hewell 165:12-23 (Nov. 4, 2022).

all of whom, are licensed pharmacists, oversaw the individual Pharmacy Supervisors, all of whom are also licensed pharmacists.[94]

All of these further process improvements were reflected in the Publix Controlled Substance Anti-Diversion Processes dated April 5, 2014.[95] This guide provided a comprehensive overview of the (1) Loss Prevention Processes; (2) Pharmacy Operation Processes; (3) Pharmacy Procurement Processes; and (4) Pharmacy Warehouse Processes. Publix continued to improve four critical aspects of its overall SOM program.

First, the PIMS Ship Max Quantities placed daily limits on the amount that could be purchased by a pharmacy.[96] These limits were established when a new product was added, and these daily limits were reviewed periodically by the Pharmacy Manager of Procurement. If an order exceeded the threshold, the order would not be fulfilled beyond the threshold and any quantity in excess of the threshold was omitted automatically and not shipped by the Publix pharmacy warehouse (without regard to its ultimate status as suspicious, or not). At the risk of stating the obvious, items not shipped by Publix's warehouse would not be available to facilitate diversion at the retail pharmacy level via the filling of illegitimate prescriptions, thus fulfilling the goal of the SOM requirement.

Second, the Pharmacy Controlled Substance Auditing Program established monthly thresholds for controlled substances by drug molecules.[97] Once the monthly threshold was met, the Publix Warehouse would not ship any more of that particular drug for the remainder of the month (without regard to any order's ultimate status as suspicious, or not). These monthly

[94] Dep. Tr. C. Hewell 162:10-16 (Nov. 4, 2022).

[95] PUBLIX-MDLT8-00067439-00067470.

[96] PUBLIX-MDLT8-00067461.

[97] Dep. Tr. C. Hewell 190:23-192:17 (Nov. 4, 2022).

thresholds are an integral component of the SOM system and were based on the analysis of historical purchasing patterns, actual pharmacy usage and usage compared to average Publix pharmacy usage. These thresholds were initially set by the Pharmacy Procurement Department and could only be increased with the approval of the Pharmacy Supervisor and the Pharmacy Operations Manager and based upon a review of information as detailed above in the description of the threshold increase review process.

Third, the Procurement Department generated monthly reports that aggregated each pharmacy's dispensing history for controlled substances.[98] These CII Pull Reports were used by supervisors to evaluate threshold increase requests and obtain insight across the entire company regarding dispensing trends for Publix pharmacies including peer-to-peer comparisons, peer rankings and potential outlier identification.[99] These reports included: (1) monthly prescription count for all controlled substances; (2) percent ratios of controlled substance prescriptions to all prescriptions; (3) count and percent of prescriptions for individual controlled substances; and (4) count and percent of controlled substances prescriptions paid for with cash.

Finally, the Publix CSOS Administrator separately, and as an additional level of compliance control, was required to review all CII orders for reasonableness prior to approving them.[100] If a pharmacy ordered more than their normal usage, the CSOS Administrator had to verify if the increase was appropriate or excessive. In making this assessment, the CSOS Administrator would consider the pharmacy's dispensing history, current inventory, allocated inventory from recent prescription activity, and a review of hard copy prescriptions.[101] Following

[98] PUBLIX-MDLT8-00067462.

[99] Dep. Tr. L. Jacobsen 114:3-116:3 (Nov. 8, 2022).

[100] PUBLIX-MDLT8-00067463.

[101] *Id.*

the review, the Manager of Procurement, a licensed pharmacist, then had to approve or cancel the order.[102]

3. In Conjunction with the Opening of the Rocket Court Warehouse, Publix Upgraded its SOM System and Implemented E-Supply Link in 2016.

Beginning in early 2016, Publix began evaluating a new electronic flagging component of its SOM system and developing a new set of Suspicious Order Monitoring System Requirements.[103] Publix was focused on improving the functionality of its existing SOM system to further analyze various order metrics reflecting volume, frequency and pattern, to establish and modify static and dynamic thresholds, and to generate additional reports.[104]

These efforts corresponded with the decision to open its new warehouse and begin self-distributing CII drugs to its pharmacies.[105] Prior to the opening of the new warehouse, Publix had never self-distributed CII controlled substances and had not self-distributed any hydrocodone since 2014 when the DEA rescheduled hydrocodone combination products from Schedule III to Schedule II. In other words, Publix had not self-distributed any hydrocodone since October 2014 and had never previously self-distributed oxycodone.[106]

Publix implemented this new system when it opened its new warehouse in September 2016, and E-Supply Link remained in use through 2020.[107] In conjunction with the implementation of E-Supply Link and the opening of the new Publix Warehouse, Publix updated its policies and procedures in the Publix Chain Pharmacy Warehouse Standard Operating Procedures dated

[102] *Id*.

[103] PUBLIX-MDLT8-00071923-00071934.

[104] *Id*.

[105] PUBLIX-MDLT8-00071926.

[106] Dep. Tr. of Publix 30(b)(6) Representative Regarding Distribution Topics 21:17-18; 22:1-5 (July 25, 2023).

[107] Dep. Tr. C. Hewell 180:24-181:16 (Nov. 4, 2022).

September 2016.[108] These Standard Operating Procedures outlined the new E-Supply Link "SOMLink" suspicious order monitoring software, which allowed Publix to timely flag, investigate, and report suspicious controlled substance orders of unusual size, pattern, or frequency to appropriate authorities. Each prescription drug order received by the warehouse was analyzed within SOMLink down to the item level prior to fulfillment and any orders flagged by SOMLink were: (a) recorded in the SOMLink application for review by a Pharmacy CSOS Administrator; (b) emailed to the Pharmacy Supervisor; and (c) deleted from the Order. Any item deleted from an order was not shipped (without regard to its ultimate status as suspicious, or not).

The Pharmacy CSOS Administrator reviewed items flagged within SOMLink on a daily basis against historical store data and comparison store order data. Orders identified by the CSOS Administrator as possible Orders: (a) of unusual size; (b) deviating substantially from a normal pattern; or (c) of unusual frequency are emailed to the Manager of Pharmacy Procurement for same-day confirmation and reporting to the local DEA field division office. Orders for greater than 7,500 unit doses of any one controlled substance in any one month must be reviewed for reasonableness.[109]

Finally, Mr. Rannazzisi places great emphasis on the fact that meeting minutes from an internal Publix Pharmacy Compliance Team Meeting indicated that E-Supply Link was not

[108] PUBLIX-MDLT8-00088238-00088391.

[109] Mr. Rannazzisi places great emphasis on the fact that meeting minutes from an internal Publix Pharmacy Compliance Team Meeting reflected a notation that E-Supply Link was not working. *See* Expert of J. Rannazzisi at p. 74; PUBLIX-MDLT8-00147799-00147800. This admission – from an attorney who was not deposed – does not affect my ultimate analysis in this matter. Publix was relying on many things beyond E-Supply Link system to prevent diversion, and, as discussed in greater detail below, the data supports the conclusion that these efforts were effective.

working.[110] The Pharmacy Compliance Team met quarterly to discuss ordering trends, controlled substance distribution and training. [111]

Importantly, Publix was relying on many things beyond E-Supply Link system to achieve the goal of DEA's SOM requirement to prevent diversion via the filling of illegitimate prescriptions, and, as discussed in greater detail below, the data supports the conclusion that these efforts were effective in fact.[112] This data is unrebutted as Mr. Rannazzisi does not rely on, and his report is devoid of references to, any data analysis whatsoever, let alone a data analysis suggesting any other conclusion.

Moreover, the E-Supply Link system was operational and did flag orders. At the same time, E-Supply Link was overly sensitive and would overflag orders of various drugs including controlled substances.[113] Another document that escaped the review of Mr. Rannazzisi was the E-Supply Link Flagging Report for the Publix pharmacies in Cobb County. [114] This report provides critical context and reveals that between 2016 and 2020, the E-Supply Link system was flagging orders for different products (including opioids), ***and*** those orders were reviewed and subject to due diligence by Publix personnel.[115] Ultimately, because E-Supply Link was unwilling to work with Publix to edit its program to reduce excessive false positives, Publix was forced to begin evaluating options to replace E-Supply Link.

[110] *See* Expert of J. Rannazzisi at p. 74 (January 24, 2024); PUBLIX-MDLT8-00147799-00147800.

[111] Dep. Tr. F. Ottolino 100:12-24; 114:2-116:8; 159:14-21 (Dec. 6, 2022).

[112] Interview of Chris Hewell on June 19, 2024.

[113] *Id*.

[114] PUBLIX-MDLT8-00148682

[115] *Id*.

4. Order Insite (2020 – Present)

In November 2018, as part of Publix's ongoing efforts to improve and streamline its compliance program, Publix evaluated another SOM system to replace E-Supply Link while also focused on centralizing many aspects of its compliance program. [116] To achieve that goal, Publix focused on three critical areas: (1) replacing E-Supply Link with a new SOM system developed by Order Insite; (2) expanding its capabilities to analyze dispensing data and maintain thorough prescriber profiles for the benefit of all pharmacists; and (3) centralizing the handling of theft and loss reporting for controlled substance inventory. The Order Insite system was essentially built from scratch and tailored specifically to Publix, and, accordingly, it took time to prepare the requirements documents and begin development of the system.[117] A tailored system has a better potential to reduce the incidence of false positives resulting from a "one size fits all", off-the-shelf program like E-Supply Link.

Order Insite was developed to provide additional scrutiny of controlled substances orders and maintain daily, weekly and monthly thresholds on a rolling 30-day basis.[118] In developing the system, Publix worked closely with Order Insite on an extensive set of design specifications regarding the company-wide use of the system, including a portion of the system, which would account for orders fulfilled by third-party distributors.[119] On July 15, 2018, Publix began testing Order Insite and distributed the Order Insite Procedure Guide. [120] Mr. Rannazzisi concedes that

[116] PUBLIX-MDLT8-00079715-00079716.

[117] Interview with Chris Hewell on June 19, 2024.

[118] Dep. Tr. C. Hewell 181:19-182:6 (Nov. 4, 2022).

[119] PUBLIX-MDLT8-00115090-00115131, 00070946.

[120] PUBLIX-MDLT8-00071715-00071733.

Order Insite appeared to satisfy the Regulations, but admits he did not analyze any of the distribution data for this time-period.[121]

C. The Publix Anti-Diversion Efforts Were Not Limited to the SOM System

Based on my review of the relevant documents and deposition transcripts, Publix has remained committed to developing and improving its SOM system and related processes. The Regulations encompass a number of requirements beyond developing and implementing a SOM system, and Publix has robust policies and procedures to address: (1) loss prevention; (2) procurement; (3) warehousing; and (4) distribution. Notably, Mr. Rannazzisi ignores certain unique characteristics that distinguish Publix's self-distribution model from that of a traditional third-party wholesale distributor.

First, through self-distributing only to its own pharmacies and hiring and maintaining quality pharmacists, Publix has an extra set of eyes focused on Publix's self-distribution and dispensing operations. This allows Publix to have a holistic view across its integrated operation from the warehouse to its pharmacies to its retail customers. Moreover, Publix maintains control over each shipment even after an order leaves the warehouse. Unlike a traditional third-party distributor, this level of control further helps prevent diversion, which can occur more easily between wholesale distributor shipping to an unrelated pharmacy. In as much as the warehouse and pharmacies are all operated under one "roof", Publix is well positioned when it comes to the DEA's "Know Your Customer" mandate. [122] Nonetheless, and without explanation, Mr.

[121] Mr. Rannazzisi "didn't analyze any dispensing data" in preparing his expert report or reaching his conclusions. Dep. Tr. J. Rannazzisi 327:13-16 (May 30, 2024). In fact, Mr. Rannazzisi has "never seen dispensing data from Cobb County[.]" *Id.* at 363:15-16. Nonetheless, Mr. Rannazzisi agrees that "dispensing data is important during the due diligence process. So a review of dispensing data and an analysis of dispensing data opens up a whole wide range, broad range of information that you could use to determine if an order is potentially suspicious or suspicious." *Id.* at 343:4-10. *See also* Expert Report of J. Rannazzisi at p. 77 (January 24, 2024).

[122] Dep. Tr. K. Wright 518:6-520:12 (Feb. 28, 2019).

Rannazzisi's report fails to consider Publix's unique situation and performs the same review he does in conventional wholesale distributing cases.

Second, Plaintiff's experts also ignore and fail to appreciate Publix's CII Pull Reports and their value in satisfying the DEA's goal to provide effective controls and procedures to guard against the theft and diversion of controlled substances.[123] The CII Pull Reports include the percentage of controlled prescriptions, patients paying cash, total prescription count, and prescription data for specific controlled substances including oxycodone and hydrocodone products self-distributed and dispensed by Publix. [124] A review of the monthly CII Pull Reports allows the order and dispensing history for an individual pharmacy to be easily compared to the other Publix pharmacies.[125] Unlike a fully integrated self-distributor like Publix, a traditional wholesale distributor does not have a similar, real-time, continuous direct line of sight into the dispensing trends for the entire universe of retail pharmacies to which it distributes.

To that end, Publix pharmacists also play an important role in maintaining effective controls against diversion for several reasons. First, pharmacists are responsible for reviewing orders of all drugs and auditing inventory.[126] Although the CSA requires an accurate controlled substance inventory every two years, Publix pharmacists conduct that inventory annually.[127] Publix pharmacists also conduct a monthly CII inventory audit and in doing so must report the thefts or losses of controlled substances to DEA.[128] Additionally, Publix pharmacists must report

[123] Neither Mr. Rannazzisi nor Dr. McCann reviewed the CII Pull Reports. Dep. Tr. C. McCann 124:15-17 (May 15, 2024); Dep. Tr. J. Rannazzisi 328:9-13 (May 30, 2024).

[124] Dep. Tr. L. Jacobsen 114:3-116:3 (Nov. 8, 2022).

[125] *Id*.

[126] PUBLIX-MDLT8-00067439-00067470.

[127] PUBLIX-MDLT8-00067455.

[128] *Id*.

suspicious activity to law enforcement.[129] Through the Publix CII Pull Reports, pharmacists are expected to evaluate their own ordering and dispensing relative to other Publix pharmacies. All of these factors allow Publix to maintain extensive control over its self-distribution operations.

As such, it is my opinion, based on its policies, procedures, inspection records, testimony, and documentary evidence, that Publix meets all federal and state regulations applicable to the distribution of controlled substances. Additionally, given its more limited self-distribution operation until, effectively, 2017, the strict controls focused on limiting orders and preventing diversion and its consistently below average dispensing of oxycodone and hydrocodone, it does not surprise me that Publix did not report any suspicious orders for the specific opioids at issue in this case until late in the relevant time period.[130] Indeed, Mr. Rannazzisi was unable to identify a single suspicious order for *any controlled substance* that was shipped by the Publix warehouse to a Publix pharmacy anywhere.[131]

VI. The DEA Inspected Seven Times During the Relevant Time Period and Has Never Taken Any Action Against Publix's DEA Registration.

The ability to maintain a DEA registration is critical for any registrant. The DEA ensures that registrants comply with the CSA and its regulations through regular physical inspections of a distributor's warehouse and related operations. DEA will not issue or renew a registration, or otherwise will take action to limit or revoke a registration, if the registrant is noncompliant and a threat to the public.

[129] 21 U.S.C. § 832. When I was with the DEA, I personally received calls from Publix pharmacists reporting potential diversion issues to me.

[130] Additionally, the obligation to report suspicious orders wasn't formally adopted until 2018 when Congress amended the CSA via the passage of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. See *U.S. v. Wal-Mart, Inc*., 2024 WL 1051017 (D. Del. March 11, 2024).

[131] Dep. Tr. J. Rannazzisi 354:2-8 (May 30, 2024).

A typical DEA distributor inspection begins with the presentation of credentials by Diversion Investigators and the signing of a Notice of Inspection (DEA-82). Diversion Investigators then meet with the key personnel who are responsible for the handling of controlled substances. The Diversion Investigators would provide a list of audited drugs and the audit period, which would be established based on the most recent biennial inventory. Diversion Investigators have broad authority to request and obtain information from registrants for purposes of completing an inspection. The Diversion Investigators would typically request, at a minimum, certain documents to assist with the audit, including, but not limited to: (1) the biennial inventory; (2) 222 forms; (3) receiving, shipping, destruction, and returns records; (4) theft/loss reports; and (5) SORs reports. In addition, SOP's for the handling of controlled substances/SOM along with a list of suppliers/customers and a company's history are requested. A security diagram may also be requested if the warehouse is fairly large. Usually the investigators request a tour of the facility while the records are being gathered and then complete a closing inventory of the drugs to be audited. Once the records are received, the investigators conduct the audit and, upon completion of the audit, a security alarm check is conducted.

A meeting with management is then conducted to outline any discrepancies wherein investigators may or may not inform the registrant about administrative actions, such as a letter of admonition (LOA). If administrative actions are taken, usually a follow-up meeting is scheduled to review the violations with the registrant. In my experience, it would be very unusual to issue an LOA to a registrant without their prior knowledge. Anything more severe than an LOA, such as a memorandum of agreement or Order to Show Cause requires communication with the registrant prior to or during execution of the action. The ROIs reflect the findings of the Diversion

Investigators, but the DEA does not provide a copy of the ROI to the registrant. Regardless, the ROI is intended to capture any issues identified by the DEA.

Before the inspection, the Diversion Investigators will review and analyze the registrant's ARCOS data.[132] Contrary to Mr. Rannazzisi's testimony, the ROIs indicate that the DEA routinely reviewed current ARCOS data in preparation for the inspections of the Publix warehouse.[133] The Diversion Investigators also review any previous ROIs in order to assess previously identified issues or violations.[134] In the event that a registrant refuses to provide any requested information, the DEA can take action against the registrant for failing to cooperate.[135] At the close of the inspection, the Diversion Investigators meet with the registrant and explain what, if any, issues have been identified.[136] The first three Publix inspections were conducted under Mr. Rannazzisi's supervision.[137]

In my experience, DEA inspections are comprehensive and thorough, and the DEA Diversion Investigators take their responsibilities seriously. DEA Diversion Investigators may hold open an investigation for as long as necessary to obtain and analyze requested information.[138] The DEA expects that the Diversion Investigators will identify any deficiencies or violations from minor recordkeeping issues to more serious infractions requiring additional action by the DEA.[139]

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[132] *See e.g.*, DEA-T711CC-00010769.

[133] Dep. Tr. J. Rannazzisi 249:14-19; 251:12-19 (May 30, 2024).

[134] Dep. Tr. J. Rannazzisi 255:3-7 (May 30, 2024); *see also* Larry K. Houck, *DEA Preregistration and Cyclic Inspections: What Applicants and Registrants Must Know in the Prescription Opioid Epidemic Age*, Food and Drug Law Institute, Update Magazine, Nov./Dec. 2017 ("Investigators prepare for cyclic inspections by reviewing previous inspection reports involving the registrant… They scrutinize areas of prior non-compliance to ensure registrants have corrected past deficiencies.").

[135] Dep. Tr. J. Rannazzisi 268:14-18 (May 30, 2024).

[136] Dep. Tr. J. Rannazzisi 271:1-8 (May 30, 2024).

[137] Dep. Tr. J. Rannazzisi 271:9-16 (May 30, 2024).

[138] DEA-T711CC-00010848-00010871; DEA-T711CC-00010939-00010942.

[139] Dep. Tr. J. Rannazzisi 267:10-19 (May 30, 2024) ("Q: And the purpose of these inspections is ultimately to protect the community to prevent the diversion of controlled substances, right? A: It's to identify violations that could create

Between 2006 and 2019, the DEA inspected the Publix distribution warehouse on five (5) separate occasions. These inspections were overseen by ten different Diversion Investigators.[140] None of these inspections resulted in the DEA taking any action against Publix's DEA Registration, and this includes those inspections which occurred during Mr. Rannazzisi's tenure as Deputy Administrator, Office of Diversion Control. Unlike Mr. Rannazzisi, I reviewed and considered all of the ROIs for the Publix warehouses between 2006 and 2021, and they appear to be consistent with my experience at the DEA.

Based on my review, it is my expert opinion that Publix's commitment to continuously improving its controlled substances compliance program to comply with the CSA is reflected in the DEA's assessment of Publix contained in the ROIs. That Publix succeeded is evidenced by the absence of any enforcement-related activity taken by DEA over the entire relevant time period, including the period Mr. Rannazzisi was "responsible for oversight and control of all regulatory compliance inspections and investigations, as well as all civil and criminal investigations" for all DEA registrants. The absence of any such activity is especially notable given the scrutiny and intensity of enforcement activity DEA applied to Florida and, in particular, the areas in Central Florida where Publix is headquartered and operates its self-distribution operations.

A. Report of Investigation dated September 10, 2008 – FY 2008 Workplan[141]

The DEA's in-depth investigation was initiated in accordance with the Orlando District Office Diversion Workplan for FY-2008 and was conducted on September 4, 2008 and September 8, 2008. The investigation was conducted by Diversion Investigators Deborah George and Linda

instances of diversion. If the inspector needs additional information from the registrant, the inspector can simply ask for it, right? A. Yes. During the daily reviews or closeout. Yes.").

[140]Mr. Rannazzisi believed that these individuals were competent, and he did not have any concerns about their ability to do their jobs as diversion investigators. Dep. Tr. J. Rannazzisi 278:5-279:6 (May 30, 2024).

[141] DEA-T711CC-00010991-00011007.

Stocum. DI George and DI Stocum conducted a thorough investigation including, but not limited to: (1) confirming that Publix held, in addition to its DEA registration, valid licenses/registrations issued by state agencies in Florida, Georgia, Alabama, Tennessee, and South Carolina; (2) conducting an accountability audit on a variety of controlled substances, including certain hydrocodone and codeine products; (3) evaluating Publix's recordkeeping practices; and (4) assessing compliance with the security requirements imposed by the CSA. The Diversion Investigators reviewed the ARCOS data and noted that controlled substances were 7% of Publix's total self-distribution of all prescriptions.[142] This ratio was well below the DEA's "reasonable" threshold of 20%.[143] The DEA also concluded that "[t]he investigation disclosed no information concerning street use of legitimately manufactured controlled substances."[144]

As part of the investigation, the DEA specifically reviewed the Publix SOM system and noted that:

> The firm's computer system sends an alert when established thresholds have been exceeded. The firm has software installed which generates orders and is programmed to establish a maximum order quantity.[145]

This was an accurate description of the Publix PIMS system that was in use at the time. The DEA did not raise any issues with respect to the Publix SOM system and ultimately concluded:

> While the firm was not cited for any recordkeeping or security violations, recommendations were made at the closing discussion held at Orlando District office on 9/8/08 relative to the form's adjustment records and their reserved/selection records. Suggestions were made to make these records more comprehensive.
>
> ***Since no further action is anticipated, this case is closed***.[146]

[142] DEA-T711CC-00010994.

[143] Dep. Tr. Kyle Wright 260:1-22 (Feb. 28, 2019).

[144] DEA-T711CC-00011007.

[145] DEA-T711CC-00011005.

[146] DEA-T711CC-00010991 (emphasis added).

As a result of this inspection, the DEA took no action against Publix. Specifically, the DEA did not issue a letter of admonition, impose any fines, or take action to either suspend or revoke Publix's DEA Registration.

B. Report of Investigation dated September 29, 2011 – FY-2011 Investigative Work Plan[147]

The DEA conducted its next inspection of the Publix Warehouse on August 1, 2011 and closed its investigation on September 29, 2011. This inspection was initiated as part of the FY 2011 Investigative Workplan for the Orlando District Office of the Diversion Control Group. The investigation was conducted by Diversion Investigators James W. Graumlich, Linda Stocum and Deborah George.

The DEA was able to confirm that Publix still held valid licenses/registrations issued by state agencies in Florida, Georgia, Alabama, Tennessee, and South Carolina. The DEA also (1) conducted an accountability audit on a variety of controlled substances, including certain hydrocodone products, diazepam, and alprazolam; (2) evaluated Publix's recordkeeping practices; (3) assessed compliance with the security requirements imposed by the CSA; and (4) reviewed the ARCOS data.

In Paragraph H(7)(F) titled Due Diligence/Suspicious Orders, DI James Graumlich stated that:

> Mr. Bamberger understood that the firm is responsible to report suspicious orders of controlled substances to the local DEA office. The firm's computer system sends an alert when established thresholds have been exceeded. The firm has software installed which generates orders and is programmed to establish a maximum order quantity based on a store's order history. If a suspicious order is received, it is flagged by the computer system and sent to a manager for review. The manager

[147] DEA-T711CC-00010717-00010736.

> contacts the store to ascertain the reason for the order and either approves or denies the order.[148]

This was an accurate description of the aspects of Publix's SOM system at that time. After completing the inspection, DI James Graumlich concluded that "there were no violations "[n]o further action is anticipated, this case is closed." In the section titled "Special Assignments," the DEA stated "Nothing to report. The file is closed."[149] Again, the DEA did not issue a letter of admonition, impose any fines or take action to either suspend or revoke Publix's DEA Registration. In my experience, Diversion Investigators are tasked with reviewing the registrant's SOM system and the DEA would have noted any potential deficiencies or issues with the SOM system if any had been identified.

C. Report of Investigation Dated July 23, 2015 – FY 2015 Investigative Workplan[150]

Pursuant to the FY 2015 Investigative Workplan for the Orlando District Office of the Diversion Control Group, the DEA conducted its next investigation of the Publix Warehouse on July 14-15, 2015. This investigation was conducted by DI Deborah George and DI Linda Stocum.

Prior to the inspection, the DEA reviewed a list of Publix's top purchasers of codeine, buprenorphine, and hydrocodone between June 10, 2013 and June 10, 2015. The DEA noted that "controlled substances account for approximately 8% of [the] firm's business."[151] When asked about the overall increase in the purchase of codeine, Compliance and Regulatory Manager Laura Slone informed the DEA that Publix had opened 38 additional stores since the previous year.[152]

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[148] *Id.*

[149] DEA-T711CC-00010734.

[150] DEA-T711CC-00010761-00010775.

[151] DEA-T711CC-00010764.

[152] DEA-T711CC-00010770.

The DEA also inquired about oxycodone purchases by five pharmacies in Florida and noted that it "was advising the firm with the understanding that there may be a valid reason for quantities purchased."[153] Chris Hewell, Manager of Procurement, also provided a detailed explanation of aspects of the Publix SOM system. The DEA kept the investigation open until it received the additional requested information from Publix. During the course of this investigation, Chris Hewell also acknowledged, and DEA was already aware, that Publix had not reported any suspicious orders to the DEA.[154]

On or about July 23, 2015, Publix responded to the DEA's request and submitted the Publix Controlled Substance Anti-Diversion Processes dated April 5, 2014,[155] the Controlled Substance Auditing Overview,[156] and the due diligence for several Publix pharmacies identified by the DEA.[157] None of the pharmacies identified by the DEA were in Georgia let alone Cobb County. After receiving the Publix response, DI George concluded that "***no further action is anticipated, this case is considered closed***."[158]

D. June 2015 Meeting with Susan Langston and Deborah George

On April 24, 2015, Susan Langston,[159] Diversion Program Manager for the DEA's Miami office requested an opportunity to meet with Chris Hewell and Laura Slone.[160] Ms. Langston stated "[i]t's Susan m the DEA. We met at the conference last week. Can you please give me a call when

[153] DEA-T711CC-00010771.

[154] DEA-T711CC-00010770.

[155] PUBLIX-MDLT8-00067439-00067470.

[156] PUBLIX-MDLT8-00140701.

[157] PUBLIX-MDLT8-00140690-00140691.

[158] DEA-T711CC-00010780-00010783.

[159] Ms. Langston worked for Mr. Rannazzisi, and he described her as honest and well-trained. Dep. Tr. J. Rannazzisi 278:3-10 (May 30, 2024). I also worked with Ms. Langston, and I share Mr. Rannazzisi's assessment of her skill as a Diversion Program Manager.

[160] PUBLIX-MDLT8-00115221.

you receive this email? I would love to have a meeting with you and some of the Publix folks. It's a good thing, not a bad thing, I promise!"[161]

Ms. Langston ultimately met with Chris Hewell, Fred Ottolino and Paul Hines. Ms. Langston communicated to the Publix representatives the view that Publix was handling its self-distribution and dispensing activities in the right way.[162] In reaction to the DEA's extensive investigation and enforcement actions against other registrants in Florida, many chain and independent pharmacies had become overly restrictive in their inventorying and dispensing of opioids and as a result, many patients, specifically in Florida, were having difficulty filling legitimate opioid prescriptions.[163] Ms. Langston encouraged Publix to continue operating in the same fashion, and the DEA appreciated that Publix was serving its customers in an appropriate manner.[164]

In my experience, interactions such as this between DEA investigators and compliant registrants are not uncommon. Moreover, this reinforces the conclusion that (1) the DEA concluded that Publix was complying with the CSA and its regulations; and (2) Publix had no reason to believe that its compliance and regulatory efforts did not comply with its obligations under the CSA.

E. DEA Issues New Publix DEA Registration in 2016

When Publix opened its new warehouse and began self-distributing Schedule II controlled substances in September 2016, the DEA granted Publix a new DEA Registration with the additional authority to handle Schedule II controlled substances. The process would have

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[161] *Id.*

[162] Interview with Chris Hewell on June 19, 2024.

[163] Kam, D., *Fed, Pharmacies Grapple with Pain Pill Dilemma*, Health News Florida (Oct. 2, 2015) https://health.wusf.usf.edu/hnf-stories/2015-10-02/feds-pharmacies-grapple-with-pain-pill-dilemma.

[164] Interview with Chris Hewell on June 19, 2024.

necessarily included an inspection of the new warehouse and an assessment of Publix's compliance programs.[165] This process involves an assessment of physical security, recordkeeping and the registrant's ability to maintain effective controls against diversion.[166] When evaluating a registrant's application to distribute Schedule II controlled substances, the DEA also considers the registrant's historical compliance with the CSA and its regulations. At the time, the DEA had the benefit of more than a decade's worth of observations of Publix's self-distribution operations. Mr. Rannazzisi described the process as the DEA doing its "due diligence" on the potential registrant.[167] The DEA considers a number of factors, and the DEA will not issue a new registration if there is any indication that the registration would be inconsistent with the public interest.[168]

In my experience, the DEA would not have issued a new DEA Registration if it had concerns with any aspect of Publix's compliance program, especially since Publix was beginning to self-distribute Schedule II controlled substances.

F. Report of Investigation dated May 15, 2017 – FY 2017 Regulatory Workplan[169]

Pursuant to the Fiscal Year 2017 Regulatory Work Plan for the Miami Field Division, Orlando District Office, Diversion Group, the DEA (Diversion Investigator James W. Graumlich) investigated the Publix Warehouse on March 29, 2017 and March 30, 2017 Diversion Investigator James W. Graumlich. ARCOS records were reviewed prior to the on-site inspection, and revealed no significant issues or violations.[170] As noted in the ROI, this was the first inspection after the

[165] The DEA would have conducted a similar inspection when it inspected the Sand Lake Warehouse in 2005.

[166] Dep. Tr. J. Rannazzisi 251:7-16 (May 30, 2024).

[167] Dep. Tr. J. Rannazzisi 252:10-13 (May 30, 2024).

[168] Dep. Tr. J. Rannazzisi 252:22-253:3 (May 30, 2024).

[169] DEA-T711CC-00010817-00010835.

[170] *Id.*

new Publix Distribution Center located at Rocket Court became operational, and it was also the first inspection since Publix began self-distributing Schedule II drugs.

Chris Hewell, Manager for Procurement, provided a detailed explanation of certain aspects of Publix's SOM system in effect at the time.[171] The DEA reminded Publix that "DEA does not approve or disapprove of a registrant's system of disclosing suspicious orders."[172]

In preparation for the inspection, the DEA had analyzed the Publix distribution data in ARCOS. Specifically, DI Graumlich, obtained a certified ARCOS report from the Targeting and Analysis Section of DEA Headquarters. This report showed all transactions reported by the firm and sales to the firm for the period in question. After reviewing this data, DI Graumlich concluded that his "***review of these records revealed no suspicious transactions***."[173] The audit period covered the period from 9/30/2016 to 3/28/2017. Notably, this time period covers the first six months that Publix was self-distributing Schedule II drugs. The DEA concluded that "no further action is necessary" and closed the file.[174] As with each previous investigation, the DEA did not issue a letter of admonition, impose any fines or revoke the Publix DEA Registration.

G. Report of Investigation date July 19, 2019 – FY 2019 Investigative Work Plan

The DEA scheduled this inspection as part of the FY 2019 Work Plan for the Miami Field Division. In preparation for the investigation, DI Roshaun McElhenny reviewed the data from the DEA Suspicious Order Reporting System (SORS), the ARCOS data and the CSOS history for the Publix Warehouse.[175] DI Richard Albert, DI Derek Urban and DI Surgeon Tate conducted the

[171] DEA-T711CC-00010821.

[172] DEA-T711CC-00010822.

[173] DEA-T711CC-00010823 (emphasis added).

[174] DEA-T711CC-00010818.

[175] DEA-T711CC-00010845.

onsite investigation on September 26, 2019, September 29, 2019 and October 4, 2019.[176] The DEA audited Publix's purchase history for various controlled substances including oxycodone, hydrocodone and fentanyl. The audit revealed no issues.[177] Although the DEA did not close the investigation, DI Richard Albert noted that "[a] review of the selected purchases and distribution records revealed no violations of DEA recordkeeping or reporting requirements."[178] DI Albert also advised Publix that "of the selected records reviewed, no violations were discovered."[179] The investigation was left open pending review of "the firm's Suspicious Order Reporting and Due Diligence Files."[180]

On November 20, 2020, DI Richard Albert met with Group Supervisor to discuss further action with the investigation.[181] The DEA decided to review the "Automated Reports and Consolidated Orders System (ARCOS) database and the Florida Prescription Drug Monitoring Program (PDMP) for the top distributed controlled substances for Schedule II and Schedule III controlled substances for Publix pharmacies." The DEA also requested due diligence files for 10 Publix pharmacies, but none of those pharmacies were located in Cobb County.

On February 16, 2021, DI Albert and DI Karen Moreno again met with Publix officials and requested additional information regarding due diligence and suspicious order reporting.[182] On March 1, 2021, Publix provided a comprehensive response including flowcharts for the Controlled

[176] DEA-T711CC-00010848-00010871.

[177] DEA-T711CC-00010849.

[178] DEA-T711CC-00010855.

[179] DEA-T711CC-00010865.

[180] DEA-T711CC-00010865.

[181] DEA-T711CC-00010847.

[182] DEA-T711CC-00010900-00010915.

Substance Ordering System and the Suspicious Order Monitoring Program.[183] On March 16, 2021, Publix provided additional clarifications regarding the Publix suspicious order review process.[184]

After reviewing this additional information, the DEA noted that this "case is being closed pursuant to Agent Manual Section 6232.32. All administrative aspects of this case have been completed. All original notes will be destroyed upon approval of this report by Group Supervisor James Graumlich."[185] As such, all aspects of the investigation were complete as the DEA only closes a case after the same and after the registrant has responded to all inquiries from the DEA.

H. The DEA Conducted Multiple Inspections of the Publix Warehouse and Reasonably Concluded That Publix Was In Compliance With the CSA.

Based on my review of the Publix SOM policies and procedures, the ROIs, deposition testimony, and other Publix documents, it is my opinion that Publix complied with its obligation under the CSA to maintain effective control against diversion. Publix justifiably relied on the DEA's repeated determinations that Publix was acting in manner that satisfied its obligation.[186] Moreover, these ROIs reveal that the DEA routinely did something that Mr. Rannazzisi did not do – analyze the ARCOS data and Publix dispensing data.[187] As discussed below, the distribution data provides further support for my opinion. Mr. Rannazzisi cannot change the fact that the DEA, under his leadership, repeatedly inspected and concluded that Publix had maintained effective controls against diversion as reflected in both the ROIs and the DEA's repeated renewals of the Publix DEA Registration over a 15-year period.

[183] DEA-T711CC-00010906-00010915.

[184] DEA-T711CC-00010923-00010936.

[185] DEA-T711CC-00010939-00010942.

[186] Dep. Tr. of Publix 30(b)(6) Representative Regarding Distribution Topics 70:5-15 (July 25, 2023).

[187] Mr. Rannazzisi confirmed he "didn't look at any statistics or data to come up with [his] opinions" because, in his own words, he "didn't have to." Dep. Tr. J. Rannazzisi 82:6-12 (May 30, 2024).

Notably, the DEA never saw the need to take any action whatsoever against Publix notwithstanding the level of scrutiny and investigation given to, and scope and scale of enforcement actions taken by, DEA with respect to, both the entire State of Florida and in particular the I-4 corridor, including the City of Lakeland (where Publix is headquartered and other registrants' registrations were revoked/sanctioned) and the City of Orlando (where Publix's pharmacy warehouse is located and other registrants registrations were revoked/sanctioned). Mr. Rannazzisi concedes this. This was during a period when the DEA had focused significant time and resources on opioid distribution issues with registrants throughout Florida.[188]

The DEA has publicly stated it:

> Uses a wide array of tools – administrative, civil, and criminal – to fight the diversion controlled substances. ***While only a minute fraction of the more than 1.8 million DEA registrants are involved in unlawful activity of this nature***, the DEA works to identify and root out the bad actors – whether they are manufacturers, distributors, pharmacies, or prescribers.[189]

This statement is consistent with my experience at the DEA, and it echoes the DEA's previous statement in the 2006 Dear Registrant Letter that "the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion."[190] The multiple inspections discussed in this section support the conclusion that Publix was clearly not one of the "minute fraction" of registrants involved in unlawful activity.

[188] Dep. Tr. J. Rannazzisi 233:7-237:14 (May 30, 2024). *See also* Ex. 7 to Dep. of J. Rannazzisi (May 30, 2024).

[189] Office of the Inspector General, U.S. Department of Justice, *Review of the Drug Enforcement Administration's Regulatory and Enforcement Efforts*, September 2019 at Appendix 4. (emphasis added).

[190] 2006 Dear Registrant Letter from J. Rannazzisi, *infra* n. 24 at p. 2.

VII. The Publix Distribution and Dispensing Data Supports The Conclusion That Publix Maintained Effective Controls Against Diversion and Was Not A Source of Diversion in Cobb County.

As discussed above, the DEA has focused on outlier pharmacies and those distributing to outlier pharmacies. This effort is logical as non-outlier pharmacies do not meaningfully contribute to diversion and, as the DEA and Mr. Rannazzisi have explained repeatedly, the vast majority of registrants are acting in accordance with their respective obligations under the CSA and the Regulations. Applying the factors identified in both the Dear Registrant Letters, Publix does not satisfy any of the identified criteria. Publix pharmacies, whether considered solely on the basis of drugs Publix self-distributed or as a customer of one of its wholesalers, were not outliers. Additionally, Publix does not satisfy any of the criteria identified in the Dear Registrant Letters.

Publix pharmacies were ***not*** ordering excessive quantities of a limited variety of controlled substances while ordering few, if any, other drugs. In fact, Publix pharmacies were ordering oxycodone and hydrocodone in lower strengths and at levels well below other Cobb County and state and national pharmacies, well below national average levels, and orders of magnitude below the egregious examples in *Southwood* and *Masters*. Publix pharmacies were also ***not*** ordering a limited variety of controlled substances that were disproportionate to the quantity of non-controlled substances. Relatedly, Publix pharmacies were complying with any applicable state laws, and they did not solicit buyers of controlled substances. Additionally, Publix was not offering to sell controlled substances without a prescription and they did not distribute to (or themselves operate) any internet pharmacies. Inexplicably, Mr. Rannazzisi does not even attempt to evaluate these factors relative to Publix pharmacies, despite being critical factors that he, himself, wanted distributors to focus on according to his letters to the distributor community.

Publix's self-distribution practices rely, in part, on the quality of its pharmacists and pharmacies, and it is therefore, critical to distinguish Publix pharmacies from the "rogue" or "bad"

pharmacies at issue in *Southwood* and *Masters Pharmaceuticals* or those identified in other tracks by Plaintiff's expert, Lacey Keller, such as Phred's Drugs as was discussed during her deposition.[191] Not only is Publix easily distinguished from these examples used by Plaintiff's experts but also from examples closer to home in Cobb County.[192]

Unlike Publix, which has never been the subject of adverse enforcement action by any governmental organization with respect to controlled substances, in early 2010 local Georgia and Cobb County government shut down the first pill mill that surfaced in Cobb County, a Pain Express Clinic in the city of Kennesaw.[193] According to interviews referenced in The Atlanta Journal article, the Pain Express Clinic caused local pharmacists, not including Publix, to "run out" of prescription pain medication within a month due to the clinic "doling out painkiller prescriptions so quickly and in such large quantities."[194]

Consistent with my experience, these types of pharmacies were the primary sources of diversion both in Georgia and nationally. Publix's self-distribution practices have nothing in common with third-party distributors like Southwood or Masters Pharmaceuticals, the distributor defendants who supplied Phred's Drugs in Rhode Island, or those distributors who provided Cobb County's Pain Express Clinic with opioids for the short time it was open. Based on my experience, the Publix pharmacies in Cobb County do not exhibit any of the indicia of diversion. Publix pharmacies were not dispensing a high percentage of controlled substances. To the contrary, Publix

[191] Unlike in this case, in other actions Ms. Keller did look at and analyze dispensing and distribution data specific to each defendant. In the case of Phred's drugs, the pharmacy purchased "more opioid dosage units from Distributor Case Defendants than any other single pharmacy in Rhode Island." Ex. 5 to Dep. of L. Keller (May 23, 2024) at p. 31. No such similar conclusion was, or can be, drawn regarding Publix.

[192] Simmons, A., *Prescription "pill mill" under scrutiny in Kennesaw*, The Atlanta Journal-Constitution (Mar. 25, 2010) https://www.ajc.com/news/local/prescription-pill-mill-under-scrutiny-kennesaw/3Qem7vh77tISJ7mbqG53iI/

[193] *Id.*

[194] *Id.*

was self-distributing controlled substances in a manner that was consistent with what you would expect from a full-service pharmacy located in a grocery store. Moreover, the dispensing of opioids was a small percentage of its overall dispensing. These percentages were below any reasonable thresholds identified by the DEA, and those percentages continued to decrease over time.

A. Publix Was Dispensing an Overall Volume of Opioids Below the Average for other Cobb County, Georgia and National Chain and Retail Pharmacies

Publix dispensing stands in stark contrast to the examples of outlier pharmacies DEA had concerns about, and even the outlier pharmacies that Plaintiffs' experts in other opioid litigation flagged as problematic. In fact, Publix pharmacies display none of the hallmarks of a bad pharmacy – particularly when compared to the dispensing of the other chain and retail pharmacies at the county, state, and national levels. Publix pharmacies in Cobb County were ordering and dispensing opioids at levels significantly below all other chain and retail pharmacies. On average, Publix Pharmacies were ordering 31.2% less than other Cobb County pharmacies, 45.2% less than other pharmacies across Georgia, and 50% less than all pharmacies nationally. [195]

[195] Expert Report of Candice Rosevear at Exhibit 3A (June 24, 2024). This chart includes dispensing data for all 14 opioids for which Publix produced dispensing data.

Exhibit 3A

Publix, Cobb County v. Purdue Pharma, et al

Comparison of Opioids Dispensed by Publix and All Other Chain & Retail Pharmacies, by Year

Dosage Units, All 14 Opiates

All Publix Stores in Cobb County

	Publix, Cobb County		All Other Chain & Retail Pharmacies, Cobb County			All Other Chain & Retail Pharmacies, Georgia			All Other Chain & Retail Pharmacies, U.S.		
Year	Total Number of Stores	Per Store Average Dispensed	Total Number of Stores	Per Store Average Dispensed	Publix Variance to Average	Total Number of Stores	Per Store Average Dispensed	Publix Variance to Average	Total Number of Stores	Per Store Average Dispensed	Publix Variance to Average
2006	24	85,341	136	126,555	-32.6%	1,949	145,544	-41.4%	63,734	169,062	-49.5%
2007	24	90,563	167	121,331	-25.4%	2,202	155,007	-41.6%	65,761	184,290	-50.9%
2008	24	99,547	141	140,310	-29.1%	2,061	169,101	-41.1%	64,752	199,381	-50.1%
2009	24	104,683	138	154,481	-32.2%	2,054	182,032	-42.5%	64,664	211,991	-50.6%
2010	24	96,640	143	154,564	-37.5%	2,078	192,217	-49.7%	65,063	223,687	-56.8%
2011	24	104,752	147	168,346	-37.8%	2,122	212,075	-50.6%	64,999	237,657	-55.9%
2012	24	118,084	150	158,772	-25.6%	2,150	208,937	-43.5%	65,779	232,840	-49.3%
2013	24	110,467	152	149,015	-25.9%	2,148	199,509	-44.6%	66,870	221,279	-50.1%
2014	24	105,741	152	144,297	-26.7%	2,186	193,974	-45.5%	66,998	214,997	-50.8%
2015	24	102,912	154	142,406	-27.7%	2,188	187,325	-45.1%	67,666	203,063	-49.3%
2016	25	98,218	145	145,504	-32.5%	2,177	184,434	-46.7%	68,533	189,439	-48.2%
2017	24	90,905	141	139,098	-34.6%	2,148	176,405	-48.5%	67,972	172,910	-47.4%
2018	24	83,994	148	121,186	-30.7%	2,311	153,729	-45.4%	68,418	149,834	-43.9%
2019	24	82,938	129	131,020	-36.7%	2,048	149,895	-44.7%	65,844	137,045	-39.5%
2006 - 2019	24	98,199	146	142,634	-31.2%	2,130	179,299	-45.2%	66,218	196,248	-50.0%

Source: ARCOS data, processed by Dr. McCann.

Notes: The "Per Store Average" is annualized for stores that exist for only part of a given year.
ARCOS provides data on the shipments of 14 opiates from manufacturers to distributors, including Chain Pharmacies. This exhibit uses the term "dispensed," which assumes that all opioid shipments to pharmacies were dispensed in the same year.

B. Publix Was Dispensing Hydrocodone and Oxycodone at a Rate Well Below the Cobb County, State of Georgia, and National Averages

As discussed in Section IV, the DEA was primarily focused on the diversion of hydrocodone and oxycodone. Publix pharmacies were consistently dispensing hydrocodone and oxycodone at levels well below any relevant geographic averages – not to mention the egregious examples such as *Southwood*, *Masters Pharmaceuticals*, Phred's Drugs, and even the Pain Express clinic example in Cobb County.

Exhibit 4B and Exhibit 4C below reflect the Publix dispensing of hydrocodone and oxycodone in Cobb County in comparison to the national average, Georgia, and Cobb County averages.

Exhibit 4B
Publix, Cobb County v. Purdue Pharma, et al
Comparison of Opioids Dispensed by Publix and All Other Chain and Retail Pharmacies, by Year
Dosage Units, Hydrocodone
All Publix Stores in Cobb County

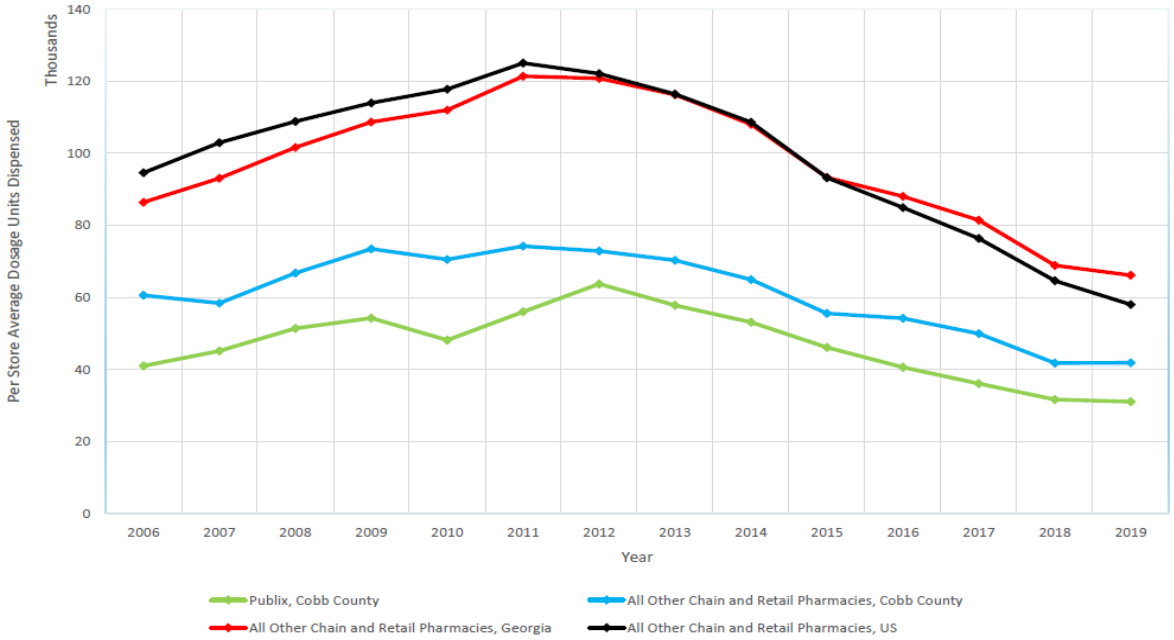
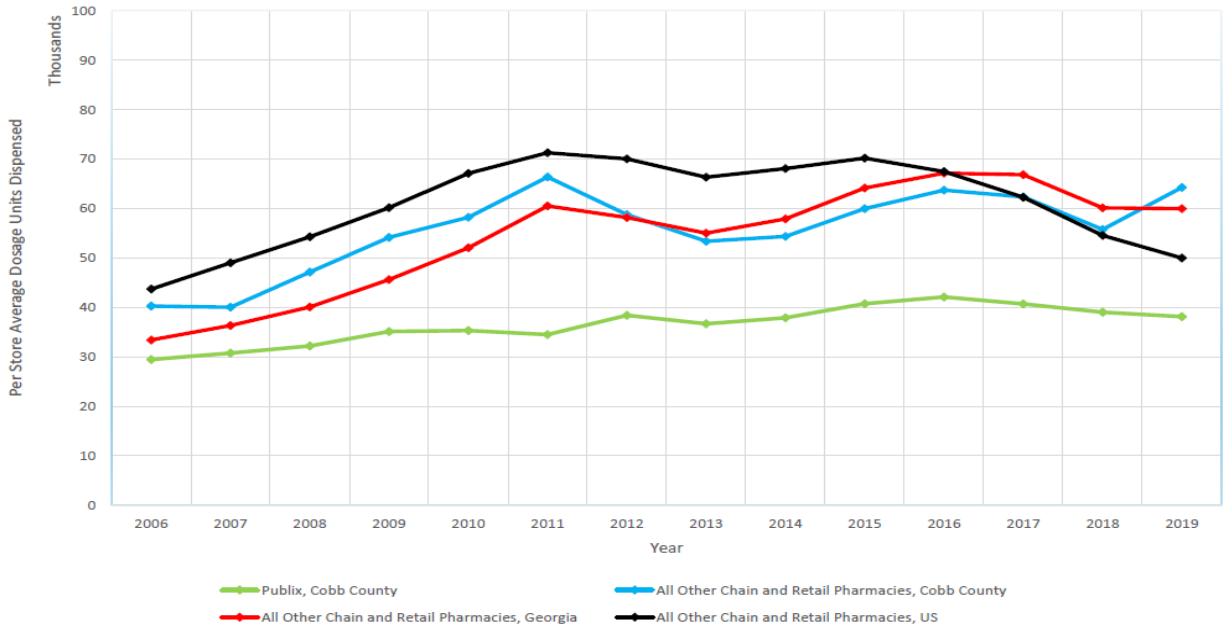


Exhibit 4C
Publix, Cobb County v. Purdue Pharma, et al
Comparison of Opioids Dispensed by Publix and All Other Chain and Retail Pharmacies, by Year
Dosage Units, Oxycodone
All Publix Stores in Cobb County



This data supports a finding that Publix kept consistent control over the controlled substances that it self-distributed and ultimately dispensed. Even beyond these two drugs, the data for all opioids dispensed by Publix indicates that its Cobb County stores were likewise well below the County average for other chain and retail stores both in terms of dosage units and MMEs dispensed each year from 2006-2019.[196] This data further underscores one of the critical failures of Mr. Rannazzisi's expert opinions in that he did not consider: (1) which controlled substances were being dispensed, (2) how much of each was being dispensed, and (3) to whom they were dispensed. Mr. Rannazzisi's report fails to consider this data into account despite acknowledging that the goal of the SOM requirement is to address diversion at the retail pharmacy dispensing level.

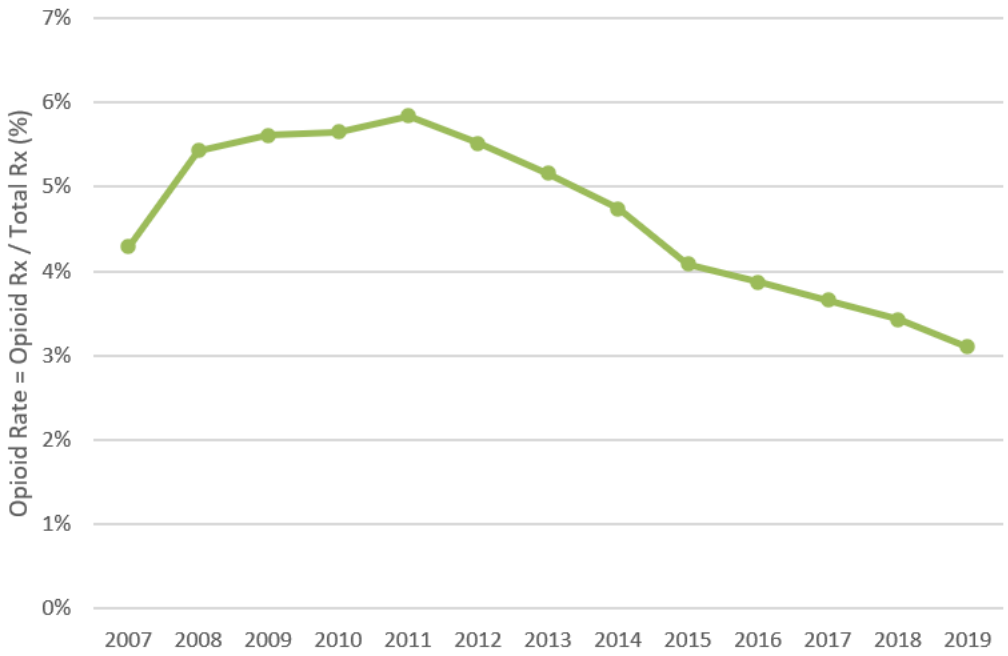
C. The Ratio of CII Prescriptions to All Prescriptions Were Consistently Reasonable for All Publix Cobb County Pharmacies

The DEA has consistently noted the ratio of controlled substance prescriptions to all prescriptions is another critical metric for identifying potential diversion.[197] The Publix dispensing data again supports the conclusion that the dispensing of opioids (and CII controlled substances more broadly) was well below the DEA's reasonable ratios. In order to analyze and reach such conclusions, I requested, and provide below, data showing the trends over time for Publix's Cobb County pharmacies dispensing of opioids as compared to all prescriptions:

[196] Expert Report of Candice Rosevear at Exhibit 3A and 3B (June 24, 2024).

[197] *See, e.g.,* Dep. Tr. Kyle Wright 260:1-22 (Feb. 28, 2019); Dep. Tr. J. Rannazzisi (May 15, 2019) ("High volume, high ratio, controlled substance to noncontrolled substance is an indicator of a potential problem, yes.").

Figure 8: Opioid Prescriptions as a Percentage of Total Prescriptions Filled by Publix Stores in Cobb County, 2007 to 2019



As indicated, the dispensing of opioids relative to all prescriptions never exceeded 6% for any of the Cobb County Publix pharmacies, and that percentage fell to just above 3% in 2019.[198] Again, this data supports the clear conclusion that Publix maintained effective controls against diversion.

Similarly, an analysis of the data shows the ratio of CII prescriptions to all prescriptions supports a comparable conclusion. Despite the fact that he testified regarding the importance of dispensing data, Mr. Rannazzisi did not actually review any Publix dispensing data.[199] In fact, Mr. Rannazzisi had no idea how Publix's dispensing compared to national, state, or Cobb County averages.[200] As shown below, however, the trend of CII prescriptions is similar to that seen with all controlled substances. Prior to the rescheduling of hydrocodone combination products from

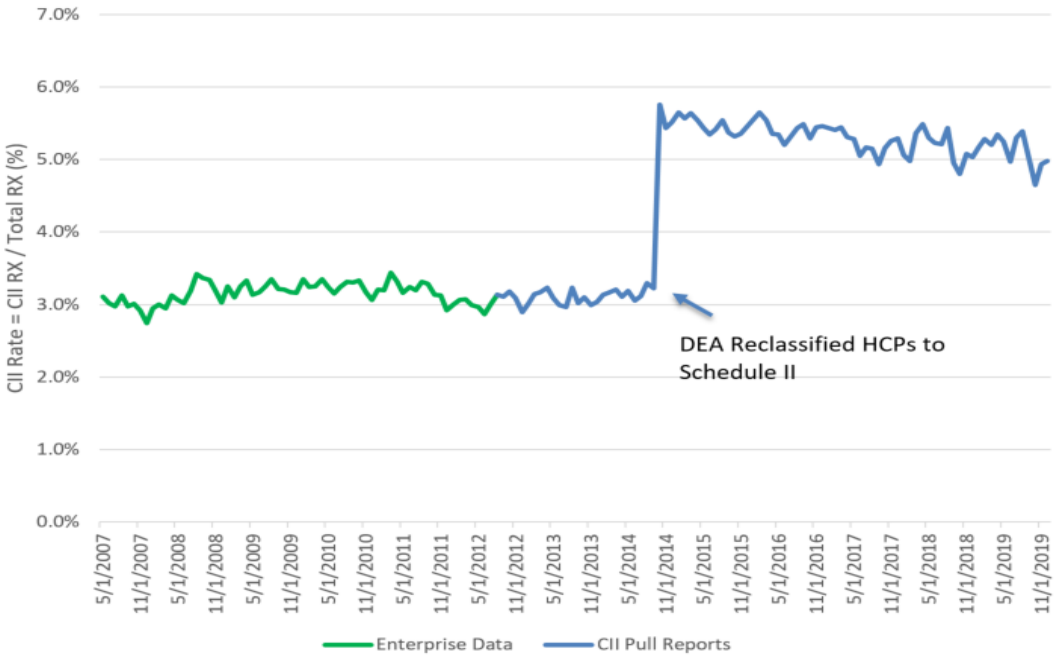
[198] Expert Report of Candice Rosevear at Figure 8 (June 24, 2024).

[199] Dep. Tr. of J. Rannazzisi 328:3-329:3; 343:4-11; 363:10-17 (May 30, 2024).

[200] Dep. Tr. of J. Rannazzisi 367:16-369:6 (May 30, 2024).

Schedule III to Schedule II, Publix pharmacies' dispensing of CII controlled drugs was approximately 3% of the total prescriptions; that percentage only increased to 5.5% (and overall continued to decrease over time) after all hydrocodone combination products were rescheduled and included in the Schedule II dispensing data.[201]

Figure 10: CII (or Schedule II) Prescriptions as a Percentage of All Prescriptions (Any Drug) Filled by Publix Pharmacies in Cobb County, 2007 to 2019



Based on this data, the ratio of CII prescriptions to non-controlled subscriptions has remained well below the levels the DEA considers reasonable.

D. The Relative Strength of Opioids Dispensed by Publix was Below the National and Cobb County Averages

Based on my experience, the DEA was concerned about the volume of a pharmacy's dispensing of higher strength opioids because with higher strength comes a greater propensity for abuse or diversion. Those who misuse opioids specifically seek out higher strength doses as Mr.

[201] Expert Report of Candice Rosevear at Figure 10 (June 24, 2024).

Rannazzisi notes in his report "hydrocodone 10 mg, and oxycodone 15 mg and 30 mg immediate release products were commonly prescribed by rogue pain clinics/rogue doctors to drugseekers/abusers in Georgia and across the United States."[202] Accordingly, Mr. Rannazzisi further concludes that the purchase of high dose/strength formulations as compared to lower strength formulations (e.g., oxycodone 30 mg compared to oxycodone 5 mg) is a critical metric for evaluating a SOM threshold.[203]

The Publix dispensing patterns, however, generally reflect a concentration of dispensed opioids in the lower strength formulations.[204] Specifically, oxycodone 15 mg and oxycodone 30 mg comprise 2.8 % and 2.7%, respectively, of all opioids dispensed by Publix pharmacies in Cobb County.[205] In addition, Publix's dispensing of higher strength opioids, as with all of its opioids, was substantially below the Cobb County and national averages other chain and retail pharmacies.[206] The data supports that Publix pharmacies were dispensing low dosage opioids for legitimate medical purposes, and these self-distribution and dispensing trends further explain why the DEA has not taken any action against Publix's DEA Registration.

VIII. Conclusion

Based on my experience and education, I offer the following opinions to a reasonable degree of professional certainty:

First, Publix has remained in good standing with respect to its central warehouse DEA Registration since it began self-distributing controlled substances in 2005. I am not aware of any

[202] Expert Report of J. Rannazzisi at p. 14 (January 24, 2024).

[203] Expert Report of J. Rannazzisi at p. 13 (January 24, 2024).

[204] Expert Report of Candice Rosevear at Exhibit 2A and 2B (June 24, 2024).

[205] *Id*.

[206] *Id*. at p. 2.

federal or state agency taking any adverse enforcement action against Publix as it relates to its self-distribution and dispensing of controlled substances. This is a clear and unequivocal indication that Publix met, if not exceeded, its obligations under the CSA and complied with the Regulations. Between 2006 and 2021, the DEA conducted five regular inspections of the Publix distribution warehouses. Based on my review of the DEA's ROIs from the regular inspections, these inspections were comprehensive and consistent with the DEA's practices. Critically, the DEA ***never***: (1) issued a letter of admonition to Publix; (2) imposed a memorandum of agreement on Publix; (3) served an administrative inspection warrant on Publix; (4) issued an order to show cause to Publix; (5) issued an immediate suspension order to Publix; or (5) otherwise took any action to suspend, terminate or revoke Publix's DEA Registration. Moreover, Publix did not encounter any issues with the DEA when it received its new DEA Registration—after undergoing additional scrutiny of its operations, SOM system, and self-distribution practices—and began self-distributing Schedule II controlled substances in 2016. Any discrepancy noted by a diversion investigator during any inspection of Publix's warehouse was addressed at the field-level and considered, at most, minor.

Second, the ARCOS data pertaining to Publix as well as Publix's dispensing data for Cobb County reinforce that its warehouses did not facilitate diversion at its pharmacies in Cobb County. Rather, the data indicate that (1) Publix pharmacies in Cobb County were ordering and dispensing opioids at levels that were expected and consistently below the national, state, and county averages; and (2) Publix was self-distributing lower strength opioids as compared to other retail and chain pharmacies. Additionally, the data indicates that the 26 Publix stores located in Cobb County were operated in a manner consistent with the obligations imposed on Publix under the CSA and demonstrates that controlled substances generally (and opioids specifically) were a small

percentage of the total prescriptions dispensed by the Publix pharmacies in Cobb County. Such analyses are critical to opining on Publix's conduct as a self-distributor because the DEA itself often uses national averages as a barometer for the distribution and dispensing of controlled substances in conducting its investigatory and oversight duties. And, when such analyses are performed, it is clear that the effectiveness of Publix's anti-diversion efforts are supported by the self-distribution and dispensing trends related to its Cobb County pharmacies.

Third, the expert report prepared by Joseph Rannazzisi suffered from several deficiencies. First, Mr. Rannazzisi completely ignores—without explanation—several critical due diligence efforts by Publix.[207] Second, and again without explanation, Mr. Rannazzisi failed to review and consider all of the DEA ROIs for the Publix warehouses. Instead, Mr. Rannazzisi's report and testimony give short shrift to the investigative work done by the DEA—including the work done by Diversion Investigators while Mr. Rannazzisi himself was Deputy Assistant Administrator, Office of Diversion Control. Third, Mr. Rannazzisi failed to review, much less analyze, the distribution and dispensing data for Publix's Cobb County pharmacies.[208] As a result, Mr. Rannazzisi's analysis of the Publix SOM system occurs in a vacuum and is devoid of any relevant context as to what Publix was *actually* self-distributing and dispensing in Cobb County. Accordingly, Mr. Rannazzisi could **not** identify a single suspicious order for any controlled

[207] For example, Mr. Rannazzisi did not review or consider Publix's use of its CII Reports. Dep. Tr. J. Rannazzisi 328:9-13 (May 30, 2024).

[208] Dep. Tr. J. Rannazzisi 328:3-329:3; 363:10-17 (May 30, 2024). As discussed in Section VII of this Report, this is inexplicable given the important role the analysis of dispensing data can play in identifying suspicious orders and preventing diversion according to Mr. Rannazzisi. Dep. Tr. J. Rannazzisi 343:4-10 (May 30, 2024) ("I agree that dispensing data is important during the due diligence process. So a review of dispensing data and an analysis of dispensing data opens up a whole wide range, broad range of information that you could use to determine if an order is potentially suspicious or suspicious.").

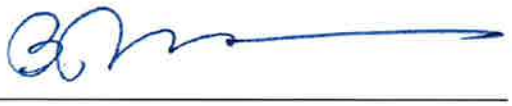
substance that Publix failed to report to the DEA, or even should have reported to the DEA.[209] Lastly, in prior cases Mr. Rannazzisi has provided an analysis of dispensing and distribution data but decided to forego such an inquiry in this case without explanation. Therefore, Plaintiff cannot support Mr. Rannazzisi's assessment using the underlying data, and I can only assume it is because the data demonstrates that Publix did have effective controls to prevent diversion.

Finally, since Publix opened its Sand Lake warehouse in Orlando, Florida in 2005, the DEA has never taken any adverse action against Publix of any kind. This is particularly enlightening given the regulatory and enforcement environment from 2006 to the present, which indicates the DEA has been vigilant in enforcing the CSA, especially in Florida. As such, it was reasonable for Publix to rely on its interactions with the DEA and conclude that it was meeting and continues to meet its obligations as a self-distributor and dispenser of controlled substances under the CSA and its Regulations. If Publix had *not* been complying with its obligations then DEA would have identified any actionable conduct and taken adverse action against Publix.[210] I see no similarities between Publix's operations and the operations of wholesale distributors like Southwood and Masters, and, in fact, there are none. In my expert opinion, Publix's conduct as a self-distributor was not a source of diversion or any oversupply of illicit controlled substances in Cobb County, Georgia, and Publix was, and is, compliant with the CSA and the Regulations.

[209] Dep. Tr. J. Rannazzisi 360:1-7; 363:10-364:5. (May 30, 2024). The Plaintiff's distribution data expert, Dr. Craig McCann also testified that, due to his lack of subject matter expertise, he was unable to identify any suspicious orders. Dep. Tr. C. McCann 51:1-7; 96:17-19 (May 15, 2024).

[210] Dep. Tr. of J. Rannazzisi 227:17-228:2 (May 30, 2024).

Executed this 24h day of June, 2024, in Scottsdale, Arizona.



Brian Rucker